EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO:	
Angela Daugherty and Jimmy Daugherty v. Ethicon, Inc., et al.	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Case No. 2:12-cv-02076	(General Prolift)

The Video Deposition of MICHAEL KARRAM, M.D., taken by the Plaintiff, pursuant to Notice and Subpoena, before Teresa A. Moore, a Registered Professional and Certified Realtime Reporter, at the offices of Frost Brown Todd LLC, 301 East Fourth Street, Great American Tower, Suite 3300, Cincinnati, Ohio 45202, on Tuesday, June 28, 2016, at 6:49 p.m.

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MICHAEL KARRAM, M.D.,
of lawful age, a Witness herein, after having been first duly sworn, was examined and deposed as follows:

EXAMINATION

BY MR. BENTLEY:

Q. Doctor, my name is Greg Bentley. I'm an attorney representing the plaintiffs in this litigation. And we're here today for your general deposition regarding Prolift. Do you understand that?

A. I do.

(Exhibit 1 marked for identification.)

BY MR. BENTLEY:

Q. I'm going to hand you what's being marked as Exhibit 1, which I believe is a clean copy of your general causation report regarding Prolift.

Does that look correct to you?

A. Yes, it does.

(Exhibit 2 marked for identification.)

BY MR. BENTLEY:

Q. Okay. I'm going to hand you, for your reference, a clean copy of your reliance list that was previously discussed in the TVT-O deposition. For purposes of this deposition, we're going to mark the reliance list as Exhibit 2. Okay?

A. Okay.

Q. All right. Doctor, when you began practicing medicine, were you treating women who suffered from prolapse?

A. Yes.

Q. How did you treat women, initially, who suffered from prolapse?

A. It would depend on the type of prolapse they had and the symptoms that they had.

Q. Okay. And what were your available options, when you began practicing, to treat women who suffered from prolapse?

A. They were do nothing.

Q. Okay.

A. They were nonsurgical options, such as pessaries or other obstructive devices or support devices that you could use to correct their pelvic organ prolapse. There were surgical procedures. And that's it.

Q. Okay. And those three options still exist today; isn't that correct?

A. They do.

Q. Okay. And with respect to the surgical options that were available when you began your career,

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what surgical options did you employ to treat women who suffered from prolapse?

A. I used traditional repairs. I used obliterative repairs. I used sacrocolpopexies. I used native tissue repairs and some augmented repairs with -- let me think back -- when did I start practice, '84 -- mostly with porcine, bovine, or other biologic materials to augment repairs.

Q. Okay. And then, today, the Prolift is no longer available; is that correct?

A. That's correct.

Q. Okay. So, in your practice today, what surgical procedures do you use to treat women who suffer from prolapse?

A. The same procedures that I just described.

Q. Do you still employ all --

A. Plus --

Q. I'm sorry.

A. Plus, I use augmented synthetic mesh procedures where I cut the mesh, individually, for the procedure that -- or the defect that I'm repairing.

Q. What kind of synthetic mesh do you use today, for your augmented repairs?

A. Most of it is polypropylene.

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Q. Okay. And who makes that?

A. There are different companies. Gynecare -- or Ethicon makes it. Coloplast has one. Bard has some. Boston Scientific has some.

Q. Do you have a preference for any one of those polypropylene meshes as opposed to another?

A. It depends on the type of procedure I'm doing and the defect that I'm repairing.

Q. With respect to Gynecare synthetic meshes, in your practice today, do you have an understanding of what specific mesh it is you're using?

A. It's Gynemesh.

Q. Gynemesh PS?

A. PS, yes. Sorry.

Q. And that's Prolene Soft --

A. Yes.

Q. -- correct?

A. Yes.

Q. Have you had any experience using meshes with a partially absorbable component?

A. I have not.

Q. You've never used any Gynecare meshes, such as ULTRAPRO?

A. I have not.

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Q. Did you ever use Prolift+M, when it was available?

A. I did not.

Q. Was there a reason why you didn't use any of the meshes with an absorbable component?

A. I was having great results with the mesh that I was using, and so I didn't see a need for it.

Q. Were the meshes with an absorbable component available to you?

A. They were.

Q. All right. Let's go back to when you began.

So, initially, these synthetic meshes weren't available, and then at some point in your career the synthetic meshes became available for prolapse repair; is that correct?

A. That's fair.

Q. Okay. And you went from using traditional obliterative SSC native augmented repairs, and then at some point Gynecare presented the Gynemesh PS; is that correct?

A. That's correct.

Q. Okay. Was that the first synthetic mesh that you used to treat prolapse?

A. Yes, I think it was. Yeah.

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Q. And that was a similar situation, where you would take a mesh and cut it yourself for the procedure that you were performing; is that correct?

A. That's correct.

Q. Okay. When you would cut a Gynecare Gynemesh PS mesh for your specific procedure, would you agree that the total amount of mesh you were using was less than what would be used in a Prolift total repair?

A. Not necessarily, because it would depend on the size of a prolapse. If you have a big prolapse or what we call a complete procidentia, where they have the entire vaginal vault everting out, that's going to require probably more mesh than a Prolift.

Q. Okay. And with your typical repair, would it be less mesh, using the Gynemesh PS versus a Prolift total repair?

A. It would depend on the anatomical abnormality.

Q. So using the -- with that understanding, using the Prolift, were there some situations where you didn't have enough mesh to accommodate the defect?

A. There were times, yes, that was the case.

Q. And that's because every patient is different?

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A. And the larger the prolapse, the more surface area you have to cover.
Q. Okay. So you started using synthetic meshes that were made by Gynecare, which was the Gynemesh PS; and then, after that, did you subsequently transition into another mesh product?
A. I've used other mesh products, but mostly kits.
Q. Okay.
A. Okay?
Q. And what was the first kit you used?
A. Prolift.
Q. Prolift. And when did that become available, if you remember?
A. I think it was around 2006 or 2007.
Q. Okay. And did you use any mesh kits made by other companies?
A. Prior to Prolift?
Q. Or -- yes, prior to Prolift.
A. No.
Q. After Prolift became available, did you use any other mesh kits made by other companies?
A. Yes.
Q. Okay. And what kits did you use?

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A. I've used Apogee and Perigee.
Q. Okay. And who makes those?
A. That was American Medical Systems.
And I've used anterior or posterior Elevate, which is also American Medical Systems.
Q. And do you have an understanding of whether that mesh construction, in the AMS products, is different than the Gynecare mesh?
A. My understanding was, they were all about the same.
Q. Do you have an understanding of whether or not they have a proprietary weaving process?
A. They may. They may. I think they may have, with the Elevate. I know, with the Monarc, they do, because they have the suture that goes through the mesh.
But I think, if you're talking about just mesh, they were both polypropylene macroporous monofilament A mid 1 type mesh.
Q. Okay. Do you have an understanding of the fact that the Gynecare Prolene mesh, using the TVT family of products, is different from the Gynecare Prolene Soft, using the Prolift?
A. Yes.
Q. And what do you understand that difference to be?

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A. It's a little lighter weight.
Q. And it has a different weave?
A. Weave.
Q. Do you find that --
MR. WALKER: I'm sorry to interrupt. But just so the record's clear, can the doctor specify which is the lighter weight?
MR. BENTLEY: Oh, sure.
BY MR. BENTLEY:
Q. Do you have an understanding of the differences between the Gynecare Gynemesh PS, and the Gynecare Prolene that's used in the TVT family of products, Doctor?
A. Yes, I do.
Q. And what is that?
A. The TVT product is a little heavier weight mesh.
Q. Okay. And the Prolene mesh that's used in the TVT products has been around for a longer time than the Gynecare Gynemesh PS; correct?
A. That's correct.
Q. Okay. So once you started using the Gynecare Prolift kit, then you subsequently also used the kits

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made by AMS; is that correct?
A. That's correct.
Q. Did you have a preference for either of those -- did you have a preference for either of the kits made by those two companies?
A. No. Most of it was dependent on the abnormality that I was treating.
Q. Okay. And could you explain to me in what situations you felt that the Prolift was advantageous as compared to the AMS product?
A. The Prolift, because of its design, in a large prolapse --
Q. Um-hmm.
A. -- it would be probably my preferred product, because it gave you better apical support with the posterior Prolift. Whereas, with the Apogee and Perigee, the Apogee never went to the sacrospinous ligament, it went to the iliococcygeus muscle, which was not as strong, whereas Prolift went to the sacrospinous ligament.
And so, in smaller anterior-only defects -- sometimes it would depend -- but I might use an AMS product in those.
Q. So is it fair to say that you didn't think

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the Prolift was necessarily the best surgical product for every patient?
A. I would agree with that statement, yes.
Q. There are some situations where you thought it was more appropriate, maybe, to use another mesh kit to treat the prolapse; is that fair?
A. Or more appropriate to even use a native tissue repair.
Q. Thank you.
So from the time when you began using the Prolift and then you began also using the AMS kits, did you begin using any other surgical kits made by manufacturers to treat prolapse?
A. I never used the Boston Scientific and I never used the Bard. So Avaulta, no; and Pinnacle and Uphold, no. So I think that was all of them.
Q. Okay. And did you --
A. If you have another one, you can give me the name, and I'll tell you if I used it or not. But I don't know of any.
Q. Okay. So then -- and then, today, as we previously discussed, the Prolift is no longer available; correct?
A. Correct.

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Q. Okay. From the time when you began using the Prolift and sometimes the AMS products, did you continue using those surgical kits through the time when the Prolift was no longer available?
A. Yes.
Q. Okay. Did you receive any Prolift-specific training?
A. I did.
Q. Where was this training at?
A. Reading, Pennsylvania.
Q. And that was put on by Ethicon?
A. It was put on by Ethicon. That's correct.
Q. And do you recall how many days that training was?
A. It was two days.
Q. Two days. Two full days of training?
A. One night and one full day of training.
Q. Okay. And that would have involved a cadaver portion?
A. Actually, no. It was on live patients.
Q. Okay. Did you watch a video component in the training?
A. Prior to that? We watched it prior.
Q. Okay.

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A. We read the IFUs. We read some company literature. But at the case, itself, no, no videos; it was all live.
Q. So you watched a video prior to attending the live surgery --
A. Um-hmm.
Q. -- correct?
A. Um-hmm.
Q. And then did you attend the live surgery led by a preceptor?
A. Yes.
Q. Okay. And how many of those live surgeries did you attend?
A. I think, that day, he did three.
Q. Three. And then, after observing those three surgeries, you then began using the Prolift yourself?
A. That's correct.
Q. Okay. Did you attend any follow-up training, after that initial training on Prolift?
A. For myself, personally? No. But I attended conferences and was a proctor in a lecture and other Ethicon courses, yes.
Q. Okay. So you taught other Ethicon courses?
A. That's correct.

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Q. Did you teach the Prolift procedure?
A. Yes.
Q. Approximately how many times did you teach the Prolift procedure?
A. I would say we probably did -- I, myself, did probably 10 to 15.
Q. And over how many years would you say that was?
A. Probably about three or four.
Q. Doctor, in your report, is it fair to say that your opinions are based on your training, experience, and review of the medical literature?
A. Yes, and education.
Q. And education?
A. Yeah.
Q. With the AMS Elevate product, did you feel there is any advantage to not having the external trocar passers?
A. No.
Q. Do you have an understanding of how many Prolift procedures you've performed?
A. I don't know the exact number, but I would say it was probably in the neighborhood of two or three hundred.

Q. And do you have an understanding of how many prolapse procedures you performed with the AMS products?
A. Probably maybe 50 to 75.
Q. So is it fair to say that the total number of mesh kits you've used to treat prolapse is 250 to 375, if my math is correct?
A. Something in that neighborhood.
Q. Okay. And then, do you have an understanding of how many prolapse procedures you've done using synthetic mesh not sold in a kit?
A. That would probably be going back early in my career. I'd say, probably in the neighborhood of, again, two or three hundred, maybe even more.
Q. In your practice today, do you have an estimate of in what percentage of the surgeries you perform to treat prolapse you use a synthetic mesh implant?
A. Today?
Q. Yes.
A. Less than five percent.
Q. And do you have an estimate, today, as to how many surgeries you perform, on an annual basis, to treat women suffering from prolapse?
A. Well, my practice is completely pelvic --

well, pelvic floor urogynecology. So if you're considering slings in that, too -- or, no, just --
Q. Just prolapse.
A. -- prolapse?
I would say 80 percent of my practice would be -- 80 to 90 percent of my practice would be that. And I, you know -- I operate two days a week -- if you want to extrapolate this thing out -- usually do three or four procedures a week. So let's say four times four is sixteen, times twelve. What's that? Get your calculator. Whatever that is. And then you calculate. And that's a year? Do you want --
Q. That's just prolapse surgeries?
A. That's prolapse surgeries.
Q. Okay. So less than 200 per year?
A. I would say, if that calculates out.
MR. WALKER: I got 182.
THE WITNESS: Close enough. Yeah, there you go?
A. (Continuing answer.) Less than 200, right. Between -- yeah.
BY MR. BENTLEY:
Q. And has that number stayed fairly consistent throughout your career or has it changed?

A. It's gotten more -- busier.
Q. Okay. In your practice, do you treat patients suffering from complications related to mesh-based products?
A. I do.
Q. Do you treat patients suffering from complications after being implanted with the Prolift product?
A. I do.
Q. What percent of your practice would you estimate is related to treating mesh-based complications?
A. Now, this does include slings; right? Yeah.
MR. WALKER: I'm going to object to the form.
A. Oh, okay. I would say, in the neighborhood of five to eight percent, maybe.
Q. Okay. So, Doctor, is it fair to say that five to eight percent of your practice, you treat women suffering from mesh-based complications? Is that fair?
MR. WALKER: Object to form.
A. I think that's an estimate, yes.
Q. Okay. Then, Doctor, do you have an understanding as to what percent of your practice is you treating women suffering from mesh-based complications

from a prolapse repair?
MR. WALKER: Object to form.
A. I would say it's probably less. In the neighborhood of maybe two to three percent or less -- two percent, I would say. I would think it's more with slings.
Q. Okay. And then, do you have an understanding of what percent of your practice you spend treating women who suffer from complications related to the Prolift procedure?
MR. WALKER: Object to form.
A. Right now, I can't really give you that amount, because the number is becoming less and less as it hasn't been being used, and we -- so I can't really give you an estimate.
Q. Can you give me an estimate of how many cases you've treated where a woman suffered complications from a Prolift procedure?
A. I'd say, probably in the neighborhood of 30 or 40.
MR. WALKER: I'm sorry, was that a number -- a total number or a percentage?
THE WITNESS: No, a total number that I've treated in my career.

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MR. WALKER: Thank you. Sorry.
BY MR. BENTLEY:
Q. Are you referred women who have been implanted with the Prolift product by another doctor and they're referred to you to treat the complication?
A. That's usually how it comes, yes.
Q. And, likewise, you may have implanted a woman with a Prolift product, and she may seek a referral to another doctor to be treated for a complication; is that fair?
A. That's fair.
Q. And you might not necessarily know that she went and saw another doctor for a complication; is that fair?
A. That's true.
Q. Okay. Doctor, have you ever reported an adverse event to the FDA, when you've treated a woman that suffered from a complication from the Prolift device?
MR. WALKER: Object to form.
A. I have not personally reported anything to the FDA or the MAUDE database, no.
Q. And would that include your office; your office, on your behalf, hasn't reported to the FDA MAUDE

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database?
A. Not directly, no.
Q. And that's not just limited to Prolift. In your practice you've never reported to MAUDE?
A. Correct.
Q. Is there any reason why you haven't reported any adverse events to the MAUDE database?
A. Because most of the adverse events that I've managed have been known complications and known risks of the surgery. So I didn't think it was related to the device, itself.
Q. It's your understanding that the MAUDE database only tracks adverse events that are related to the device specifically?
MR. WALKER: Object to form.
A. I think, yeah. That's what I thought.
Q. Today, do you have a preference for any of the surgical treatments for prolapse?
MR. WALKER: Object to form.
Are you asking about anterior, posterior, or just more generally?
MR. BENTLEY: General.
A. I mean, there is no one procedure that's going to treat all.

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BY MR. BENTLEY:
Q. Right.
A. So if you're asking if a patient came in to me, what would my -- what would I be the most happy with taking care of? An obliterative procedure, because it takes care of the problem and it's an hour procedure and everybody's happy.
Q. Okay. That's fair.
A. But it depends on the situation.
Q. Okay.
A. Every clinical situation, usually, is very unique to the individual and her anatomy, and it depends on what her complaints are.
Q. Right.
A. And then you tailor the treatment based on that.
Q. It's fair to say, the obliterative procedure is probably not the most common procedure to treat prolapse?
A. It's not, but you sure wish it was. But you're right. No, it's usually an elderly lady who's not sexually active and it's more of a sanitary issue than anything else.
Q. When the Prolift kits were available, do you

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have an understanding of what percentage of your surgeries to treat prolapse you used Prolift for?
A. When I started using Prolift and first -- in the first few years, I was using it probably about 20 to 30 percent of the time, maybe more.
Q. Okay.
A. But it's hard to estimate.
Q. And then, with the remainder percentage, how could you estimate what other procedures you were using? Some of that -- some of those other surgeries would entail the AMS product; right?
A. Or they would entail a native tissue repair --
Q. Okay.
A. -- or a sacrocolpopexy --
Q. Right.
A. -- something like that.
Q. And can you estimate for me what percentage of your other patients would be native tissue repair?
A. I would say the majority of them were native tissue repair.
Q. And is that still true today?
A. Almost all of them are true, yes. Much higher today, now, because we don't have the kits.

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Q. Do you have good results with native tissue repair?
A. It depends on the procedure. It depends on the procedure and the anatomy that we're dealing with.
Q. So is that a yes?
A. Yes.
Q. Do you have an understanding as to what percentage of your patients you treat with native tissue repair have to undergo a repeat operation because that initial procedure didn't work for the prolapse repair?
A. I don't. I don't have a percentage, no.
Q. How long would you typically follow up with a patient after you'd implanted a Prolift product?
A. I would see them back at two weeks, four weeks, six weeks; and then I would see them back at six months and a year; and then, thereafter, if they were doing fine and not having any problems, I would see them back yearly.
Q. Do you have an understanding as to whether Prolift complications can arise after the one year?
A. I'm sure they can.
Q. Did you experience that with any of your patients?
A. There were a few, yes.

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Q. Have you read any literature that evidences women suffering from complications well past one year from their Prolift procedure?
MR. WALKER: Object to form.
A. I have. And I have also seen patients like that from other physicians, yes.
Q. When Prolift is available and you're talking to your patients about the risks and benefits, that would be a conversation between you and the patient to make a joint decision; is that fair?
A. That's fair.
Q. Okay. And you, as a doctor, would be educating the patient as to the risks and benefits of the product and the alternative procedures; is that correct?
A. That's correct.
Q. And you'd want to give the patient as much information as possible, so they can make an informed decision as to whether or not to undergo that procedure versus another procedure; is that fair?
MR. WALKER: Object to form.
A. That's correct.
Q. Okay. And what would you tell the patient, specifically, were the benefits as to using the Prolift procedure?
A. Well, if somebody came in and they were a recurrent prolapse, I would say, your native tissue repair that Dr. So-and-So did was not effective; you had a failure; and if we do another native tissue repair, the likelihood is you're going to have another failure; but we have a product available that's a mesh-based product, and I've had good results in my hands, and I think she'd be a great candidate for this. And then she would ask me questions, and we would discuss the issue and come up with a plan of action.
Q. So you would inform the patient that the Prolift product could be favorable in a situation where a previous surgery may not have had a successful outcome to treat prolapse; is that fair?
A. That would be one, yes.
Q. So, Doctor, in your eyes, you viewed a favorable patient for the Prolift as a patient who is maybe high risk or had failed at a previous surgery; is that fair?
A. That would be one, yes.
Q. Were there any other benefits you would describe to a patient, when you're undergoing the informed-consent process discussing whether or not to undergo a Prolift procedure?
A. The size of her prolapse. The larger the size and the more advanced the stage, the less likely she was going to get a really good repair with a native tissue repair.
Q. Okay. When you were discussing whether or not to undergo a Prolift procedure with a patient in the informed consent, would you discuss some of the medical literature with your patients?
A. I would give her my experience with it. And then, I wouldn't actually cite specific medical literature --
Q. Okay.
A. -- no.
Q. Would you discuss the medical literature might show a range of success rates, for example?
A. I would say yes. Yes.
Q. Okay. So I'm guessing you never gave your patients medical literature to take home with them?
A. I did not.
Q. Is it fair to say that you've stayed abreast of the medical literature regarding Prolift, from when you began using the product?
A. I've tried, yes.

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Q. Would you agree that some doctors don't have time to review all the literature?
MR. WALKER: Object to form.
A. It's tough to keep up with all the literature, yes. That's correct.
Q. And would you agree that some doctors likely aren't as knowledgeable about the Prolift literature as you might be, for example?
MR. WALKER: Object to form.
A. I'm sure there probably are people like that.
Q. And even you were in a special place, because you were actually proctoring for the Prolift procedure for Ethicon; isn't that correct?
MR. WALKER: Object to form.
A. That's correct.
Q. So you were probably well educated in the medical literature regarding the Prolift, as compared to some other doctors?
MR. WALKER: Object to form.
Q. Is that fair?
A. I would hope so, yes.
Q. In the informed-consent process with a patient, what risks would you discuss with your patients?

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A. I would tell them --
MR. WALKER: And this is for Prolift; right?
MR. BENTLEY: Yes.
A. Yeah. I would tell them that anytime you have surgery, you have anesthetic risks, risks of infection, hemorrhage, urinary tract injury, bowel injury. Risks associated with synthetic mesh: Erosion, extrusion, dyspareunia, pelvic pain, the possible need for another procedure to correct these problems if they do occur.
Q. And you mentioned risks associated with a mesh implant; is that fair?
A. And I would also give them the same risks with a native tissue repair. The only difference is, no mesh.
Q. That's fine. Now I want to talk about the mesh complications --
A. Okay.
Q. -- specifically.
A. Okay.
Q. What complications, related to the mesh implant specifically, would you discuss with your patients?
A. I thought I just told you that.

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Q. I'm sorry. I didn't --
A. All right. Specifically to the mesh would be urinary tract injury, bowel injury, erosions, extrusions, scarring, pelvic pain, dyspareunia, and the possible need for another procedure to correct one of those problems, if they did occur --
Q. And some --
A. -- that would be specific to the Prolift.
Q. And sometimes there might actually be multiple procedures; is that fair?
A. That's correct, yes.
Q. Would you discuss the frequency of any of those risks, when you're performing the informed-consent process with the patient?
A. I would.
Q. And where would you draw that frequency information for those risks from?
A. The medical literature available to us. And, from the time it was available to now, obviously there's more medical literature than there was before. So...
Q. Would you discuss the severity of any of those complications with your patient, when doing the informed consent regarding a Prolift procedure?
A. It's hard to quantify "severity." I think

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any patient believes that when they have a complication, it's severe, regardless of how minimal or how maximum it is. So it's hard to quantify "severity."
Q. But you understand, some women have suffered life-changing complications as a result of the Prolift procedure; is that fair?
MR. WALKER: Object to form.
A. I'd have to look at that case specifically. I'm sure there are women that have had problems with the procedure. But until I actually examined the -- you know, the procedure or the patient's medical records and saw exactly what happened and what took place, I can't really say that, you know, I know for a fact that there are people that have life-threatening complications related to the Prolift. I can't say that.
Q. You haven't read medical literature discussing women that had serious complications after a Prolift procedure?
A. I've read literature that have complications. And, like I said, everybody considers a complication serious. But I've also seen those patients, and we've managed those patients and they've done fine and they don't have any long-lasting, life-threatening -- or life-changing complications. They go about their

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business and they live a normal life.
Q. Just so I'm clear --
A. Yes.
Q. -- it's your opinion that some women might have a complication, but they don't have life-altering complications?
MR. WALKER: Object to form.
A. How do you define "life-altering"?
Q. Doctor, are there attendant risks with any surgery?
A. Absolutely.
Q. And so, if you're subjecting a woman to multiple repeat surgeries to repair a complication related to Prolift, do you think that's important?
A. I think that's important. That's correct.
Q. Do you think she would consider that serious?
A. She considers the first complication serious.
MR. WALKER: Object to the form of the question.
Q. And each time you're adding on another procedure, that increases the risks associated with it; isn't that fair?
A. Not necessarily. It depends on the procedure you're doing and how good you perform the procedure.

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Q. There's not increased risk with each subsequent pelvic surgery?
A. Well, these aren't pelvic surgeries; they're vaginal surgeries.
Q. It's in the pelvis; right?
MR. WALKER: Object to the form.
A. It's outside the pelvis. The pelvis is above the pelvic floor. This is below the pelvic floor.
Q. So it's your opinion that additional surgeries carry no increased risk?
A. No, I didn't say that. I think additional surgery -- every time you do a surgery, there is more risk. Yes, I agree with that.
Q. And as you go along that stratosphere of increased surgeries, wouldn't you consider that a serious complication?
A. I would consider it a serious complication, but it doesn't necessarily have to be life-altering. I think that the phrase, "life-altering," is kind of --
Q. You just don't like the phrase, "life-altering"?
MR. WALKER: Object to form.
A. I don't think it's appropriate.
Q. Okay. Is there a better medical term to

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discuss women who have had to undergo repeated multiple surgeries to treat complications related to Prolift, that you would prefer to use in this deposition, Doctor?
MR. WALKER: Object to the form.
A. I would just like to say they've had multiple procedures to deal with multiple complications.
Q. Okay.
A. Okay?
Q. Doctor, we discussed some complications that you feel were unique to mesh. And I wanted to see, would you agree that contraction of mesh is a unique complication to mesh implants?
MR. WALKER: Object to form.
A. I don't agree that mesh contracts.
Q. That wasn't exactly my question. It might be a bad question.
But --
A. Okay.
Q. -- absent mesh implant, can you have contraction of mesh? Obviously not; right?
MR. WALKER: Object to form.
A. If you say mesh contracts when it goes in the bodies, and that's your opinion, and you don't put mesh in the body, yes, it won't contract.

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MR. BENTLEY: I want to strike that as nonresponsive.
BY MR. BENTLEY:
Q. And we'll look at some literature.
So it's your opinion that mesh contraction doesn't exist?
A. It's my opinion that the body incorporates in the mesh and the actual fibrosis of the incorporation causes contraction. But I don't --
MR. BENTLEY: Appreciate that. I'm going to strike that as nonresponsive.
And, with all due respect, Doctor, we have two hours. And I'm going to ask just if you can try to answer my question. I might have had a bad question. That's fair. If you'd like me to rephrase it, that's fine.
THE WITNESS: Okay.
BY MR. BENTLEY:
Q. Is it your opinion that there's not mesh contraction related to Prolift implants?
A. What's your definition of "mesh contraction"?
Q. Is it your opinion that the medical literature does not refer to mesh contraction?
A. The medical literature shows that there isn't

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any mesh contraction.
Q. And that's your opinion?
A. That's in the medical literature.
Q. Okay. Is it your opinion that mesh does not become bunched up once it's implanted?
MR. WALKER: Object to form.
A. That's correct.
Q. And it's your opinion that the medical literature does not reference and evidence mesh becoming bunched up once it's implanted?
A. Mesh can become bunched up, but it's at the time of implantation, not later on.
Q. Is it your opinion that mesh retraction happens after implantation?
A. What's your definition of "mesh retraction"?
Q. Is it your opinion, Doctor, that the medical literature does not document mesh retraction related to Prolift implants?
A. How are you defining "retraction"?
Q. If you'd just please answer my question, Doctor.
A. I don't have an answer to that, because I don't know what you mean by "retraction." Does it --
Q. I'm not -- that's not my -- my turn, Doctor.

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My question, specifically: In your opinion, does the medical literature reference mesh retraction related to Prolift implants?
MR. WALKER: Object to form.
Q. Yes or no?
A. In vivo,in vitro, in dogs, in rats? What literature are you referring to?
Q. That's fair.
Doctor, does the medical literature studying women who have undergone Prolift implants in vivo --
A. Um-hmm.
Q. -- does it reference mesh retraction?
A. I think there are articles that will reference that, yes.
Q. But you disagree that that is an occurrence?
A. I disagree.
Q. Okay. Have you ever treated a woman who's suffered from mesh retraction?
A. I can't answer that question.
Q. Fine. Have you ever treated a woman who suffered mesh contraction?
A. Again, I can't answer that question.
MR. WALKER: Object to form.
Q. Have you ever treated a woman who suffered

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from bunched mesh?
MR. WALKER: Object to form.
A. Yes.
Q. And what happens when the mesh becomes bunched, after a Prolift procedure?
A. It rolls in on itself because it probably wasn't placed correctly.
Q. Okay. And that can lead to pain?
A. That can lead to pain, yes.
Q. And that can lead to removal of the mesh?
A. Yes.
Q. Which can be an invasive procedure?
A. Correct.
Q. And lead to --
A. And, well, sometimes.
Q. Okay.
A. And sometimes it can be noninvasive, if you consider using nonsurgical methods, which can help, or noninvasive medicine -- or techniques, where you use -- remove it in the office.
I don't know if you would consider that invasive. I don't.
Q. All right. Sometimes bunched mesh can lead to multiple removal surgeries; isn't that true?

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A. That's correct.
Q. And sometimes, even after those multiple surgeries, a woman still suffers from pain; isn't that correct?
A. There are some, yes.
Q. Doctor, do you keep a case log of all the patients you've perform surgery on?
A. In my entire career? No.
Q. Doctor, do you have an understanding, today, as to why the Prolift is no longer available?
A. It would just be some -- a hypothetic, my thought. I don't know. I don't know why, other than I think the companies didn't want to deal with the legal issues. I think. I don't know. That's just my opinion. I don't know.
Q. And on your reliance list, there's a number of internal Ethicon documents, close to 500; right?
A. Yes.
Q. And in any of those documents, it didn't discuss why the Prolift is no longer available?
A. None that I saw.
Q. Did any of those documents discuss a 522 order?
A. I think so, yes.

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Q. Okay. Do you have an understanding as to what a 522 order is?
A. Yes.
Q. Could you describe that, please?
A. It's a more extensive trial to get a product approved by the FDA.
Q. And you've previously testified you're not a regulatory expert; right?
A. That is not -- that's correct, I'm not a regulatory expert.
Q. And that's true today; right?
A. That's true, today, absolutely.
Q. Doctor, in reaching your opinions today, is the FDA's analysis of the studies regarding the safety and the efficacy of the Prolift device -- are those -- is that analysis of those studies important to you?
A. It is.
Q. Do you think the FDA has scientists and epidemiologists that are highly qualified to look at that type of data?
A. I'm sure they do.
Q. And if the FDA reviewed the literature and came to a conclusion that the safety and effectiveness of Prolift had not been reached through that literature,

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would that be important to you?
MR. WALKER: Object to form.
A. It would.
Q. Would you agree that the FDA's viewpoints as to whether there's a need for more rigorous studies regarding the safety and efficacy of Prolift -- is that important?
MR. WALKER: Object to the form.
A. It is.
Q. Did you take any of the FDA's analysis of the medical literature regarding Prolift into account, when you were forming your opinions here?
A. I took the FDA notices into account, yes.
Q. And you're talking about the public health notices?
A. That's correct.
Q. Okay. So if the FDA had requested Ethicon to perform additional, more rigorous studies regarding the Prolift procedure because the FDA concluded that the current literature was insufficient to establish the safety and efficacy, that would have been important to your opinions here?
MR. WALKER: Object to form.
A. I think that would be important. But it's

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not important to my opinions.
Q. I don't understand.
It would be important to your opinions here or --
A. But -- yeah. But it doesn't change my opinion of the procedure, the device, and the indications, and the use of it.
Q. It might impact your opinions regarding the medical literature, but it wouldn't impact your opinions regarding your personal experience; is that fair?
A. Yeah, that's fair.
Q. Would you like to see that analysis, if it existed?
A. An FDA analysis of Prolift?
Q. I'm sorry. That was a bad question.
A. Okay.
Q. That's fair.
If the FDA did undertake an analysis of the medical literature, regarding the safety and efficacy of Prolift, and concluded that it was insufficient, would you have liked to have seen that analysis --
MR. WALKER: Object to form.
Q. -- in preparing your report here?
A. If that analysis existed, yes.

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Q. Because it might inform your opinions regarding the medical literature here; right?
MR. WALKER: Object to form.
A. Possibly.
Q. Okay. So, Doctor, is it your testimony, today, that you don't know whether or not the FDA did request Ethicon to perform additional studies on the Prolift procedure?
A. I'm not -- yeah, you're right, I don't know that.
Q. Okay. And you don't know if Ethicon chose to withdraw the Prolift from the market instead of doing those studies? You don't know that; right?
A. I don't know that.
MR. WALKER: Object to form.
Q. If Ethicon did withdraw the Prolift instead of doing the 522 studies, would you like to know that?
MR. WALKER: Object to form.
A. It would be hard, unless you understood the context of what it was all about. I mean, you know, to do more studies is very expensive, and to get randomized control trials and to recruit patients. So it might not just be because they don't want to do it because they feel that the product isn't good; it might be that just

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from a financial and economic standpoint, they can't do it. So...

Q. But you don't know, because you haven't reviewed --

A. I don't know.

Q. -- those documents?

A. Yeah, I don't know.

Q. So would you have liked to be able to review those documents demonstrating the process and the discussions, to see the full context of why the Prolift was pulled from the market?

MR. WALKER: Object to form.

A. I don't think it really matters. I mean, they have to make a decision as a company. Other companies made a decision to move forward with their mesh products and to go ahead and do the randomized control trials. And companies are doing that.

So, you know, to me, it's a company decision; it's not -- it really doesn't have any relevance or -- on my decisions or my opinions.

Q. Do you know if -- I probably know the answer.

But do you know if Ethicon tried to convince the FDA to accept studies that already existed, rather than doing new studies, as requested by the FDA?

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MR. WALKER: Object to form.

A. I don't know if that happened. But I know that's pretty standard in the industry. When the FDA asks for more information, then companies go back and say, well, we have more information, look at these studies, review this, and things like that. So -- but I'm not --

Q. I'm sorry.

A. Yeah, go ahead.

Q. And you testified that other companies, in fact, did do more studies; isn't that fair?

A. Well, actually, AMS started to, and then they pulled out.

Q. Okay.

A. So they do not have their 522 on Elevate anymore, it's gone; and they don't have their capture study, it's gone.

Q. Doctor, you don't hold yourself out as an expert in epidemiology, do you?

A. For sure not.

Q. When you cited data in your report from the medical literature, was it important to you to approach the issues in an objective fashion?

A. It was.

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Q. Okay. And was it important for you to approach the issues in a fair and balanced way, to give a full picture of the important data?

MR. WALKER: Object to form.

A. I tried, yes.

Q. Because that's important to you, as being an objective expert; right?

A. That's correct.

Q. And would you agree that it was your obligation to give both sides of the story, to the extent both sides of the story were presented in an article?

MR. WALKER: Object to form.

A. Correct.

Q. You wouldn't want to cherry-pick only favorable evidence from an article or ignore data that's contrary to your opinion?

A. No, definitely not.

Q. Because that wouldn't be objective; right?

A. Correct.

Q. Doctor, in forming your opinions regarding the Prolift device, did you rely on TVT data to form any of your opinions regarding the safety and efficacy of Prolift?

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A. Only in the sense of cytotoxicity, carcinogenesis, and some of the other products that are mesh products that plaintiffs are saying cause problems.

Q. So you're only relying upon TVT literature regarding cytotoxicity and carcinogenesis?

A. I'll tell you -- no. I'll tell you exactly what I'm relying on.

It would be degradation and particle loss. It would be pore size and weight; malignant potential of mesh; biocompatibility of mesh. And that's it.

Q. Cytotoxicity, carcinogenesis, degradation, pore size and weight. And what was the last --

A. Biocompatibility of mesh.

Q. Okay. Doctor, you previously testified that the TVT Prolene mesh is a different weave as compared to the Gynecare Gynemesh PS; isn't that correct?

A. It's a heavier mesh, yes.

Q. Because it has a different weave; isn't that correct?

A. Um-hmm.

Q. Which, necessarily, involves a different amount of polypropylene filament that's woven together; right?

A. I'm not an expert, but I think so, yes.

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Q. Okay. And that means it's going to have a different pore construction or geometry; wouldn't you agree with that?
A. It may change it, yes.
Q. If it has a different weave, obviously it's going to be a different --
A. Correct.
Q. -- design; right?
A. Correct.
Q. And so it's going to -- as you said, it has a different weight; right?
A. Yes.
Q. Okay. So do you still think it's reliable to rely upon the TVT literature regarding pore size and weight, when you're looking at the safety and efficacy of the Prolift device?
A. I think so.
Q. Can you explain why you think a different mesh with a different weave is relevant to the Prolene mesh with a different weave, regarding pore size and weight?
A. Well, because the pore size is macroporous and it's monofilament and it's a Type 1. And so, even though it's a little heavier, it reacts the same.

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Knitted mesh has a high porosity and -- just as I state here. So...
Q. So, to you, any knitted mesh made of polypropylene --
A. Not necessarily. In these two it does.
Q. Okay. And what analysis did you undertake to come to that conclusion, that the TVT literature regarding pore size and weight is relevant to the Prolene mesh -- I'm sorry, to the Prolene Soft mesh used in the Prolift device?
A. The Prolift studies that ratify the mesh properties.
Q. Can you identify what Prolift studies indicate that the TVT literature is relevant for these biomechanical --
A. Well, I don't think --
Q. -- properties?
A. -- it's the TVT literature. It's the mesh used in synthetic slings.
Q. Okay. And can you identify any studies, as you sit here today, that indicate the biomechanical properties of the TVT mesh is related to the Prolene Soft mesh, regarding the safety and efficacy?
A. I can't quote any now, no.

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Q. Okay. Do you know whether Ethicon internally thought the TVT data and studies should not be considered, regarding Prolift?
MR. WALKER: Object to form.
A. I do not.
Q. Would you defer to Ethicon's viewpoint, regarding the construction of the mesh and what evidence is relevant?
MR. WALKER: Object to form.
A. I would.
Q. If there were some analysis or documents that existed discussing those very issues, would you have liked to have seen those?
A. Yes.
Q. Because that could impact your opinions in your report; isn't that fair?
A. Possibly, yes.
Q. Okay. Do you know whether the FDA thought that TVT data and studies should not be considered regarding the Prolift?
MR. WALKER: Object to form.
A. No, I don't.
Q. Again, would you defer to the FDA's viewpoint on such matters?

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A. I would.
Q. And we discussed that the Prolift is no longer available, but the TVT products are available on the market still; right?
A. That's correct.
Q. Okay. And the TVT products use a different weave, which is Prolene; correct?
A. Correct.
Q. Okay. Doctor, can you explain any of the biomechanical differences between the Prolene mesh used in the TVT and the Prolene Soft Gynemesh that's used in the Prolift?
A. I really can't. I'm not a biomechanical --
Q. You would defer --
A. -- engineer.
Q. -- to a biomechanical expert?
A. Engineer, right.
Q. And, likewise, you don't know the clinical impacts of those biomechanical differences, do you?
A. Only in comparison to patients that I've treated with both of them.
Q. Can you identify any evidence discussing or evaluating the clinical impacts of the biomechanical differences between the TVT products and the Prolift

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Gynemesh Prolene Soft?
A. I can't, no.
Q. Would you agree that the TVT implant uses a much smaller piece of mesh, as compared to the Prolift mesh?
A. Yes.
Q. Doctor, did you review any of the clinical data regarding the Prolift product in those Ethicon internal documents that are on your reliance list?
A. Any clinical data?
Q. You have a number of articles listed in your literature section; correct?
A. Right.
Q. Okay.
A. Right.
Q. And then, aside from that data, is there -- do you have any understanding that you reviewed any of the clinical data, aside from the publicly available stuff, that was provided to you from the internal Ethicon documents?
A. No.
Q. Would you have liked to review any of the internal French TVM data, in reaching your opinions here?

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A. I've seen some of the TVM French material. So I've reviewed some of that.
Q. In the internal Ethicon documents or in the published literature?
A. In the published literature.
Q. Would you have liked to have seen the internal documents Ethicon has regarding those studies?
A. I think the published literature's in peer-reviewed journals, and it really doesn't matter.
Q. But you don't know what's in those other documents, do you?
A. I do not.
Q. How did you decide which studies to cite in your report, Doctor?
A. Oh, I tried to do a search of all the mesh products that were out there, and specifically in relationship to Prolift, and reviewed them all as best I could.
Q. Let me make sure I understand.
A. Yeah.
Q. So you have a number of scientific articles listed on your reliance list?
A. That's correct.
Q. Okay. But not all those articles are

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discussed in your report; right?
A. Correct.
Q. Okay. And I'm not sure that would be even feasible, honestly.
But how did you decide which articles to discuss in your report?
A. I guess I looked at the most scientific, which would be the meta-analyses, the randomized control trials, the trials that had large patient numbers, the trials that were maybe done at one center or where you could rely on the fact that the procedures are reproducible. But, yeah. But it is mainly the more scientific ones, the meta-analyses and the randomized control trials.
Q. So you tried to focus your review on Level 1 evidence, which is meta-analyses or systematic reviews?
A. There you go.
Q. Okay. And RTCs; is that fair?
A. Correct.
Q. Okay. And those are the studies you tried to discuss in your report, because you felt those were more informative on the issue as to the safety and efficacy of the Prolift device --
A. I think they --

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Q. -- is that fair?
A. -- carry a higher weight, yes.
Q. And you didn't deliberately decide not to cite studies in your report that were unfavorable to Prolift; right?
A. No.
MR. WALKER: We've been going almost an hour. Do you need a break?
(Brief recess taken.)
BY MR. BENTLEY:
Q. Doctor, we're back from a short break. Are you ready to go?
A. I am.
Q. Okay. Doctor, if you could please turn your attention to your report, which I believe we marked as Exhibit 1.
A. Um-hmm.
Q. On page 21, you have a section that begins, "Adequacy of Company IFU and Patient Brochures."
A. That's correct.
Q. Do you see that?
A. Yes.
Q. Okay. And in this section, you discuss adequacy of the warnings; is that correct?

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A. That's correct.
Q. It's your opinion, that you intend to offer to the jury, that Ethicon adequately warned doctors regarding the complications of the Prolift device; is that correct?
A. Yes.
Q. Okay. And you explain, on page 22, that one of the bases for your opinions is that although you're not a regulatory expert, you've reviewed 21 CFR 801.
Do you see that?
A. Yes.
Q. Okay. And how did you come to review 21 CFR 801, Section 109?
A. I was looking for a -- some kind of a document to support the fact that any pelvic floor surgeon that has experience in pelvic floor surgery, whether it's mesh or non-mesh, and he start -- he or she starts to use any kind of products, does the company have the responsibility to let them know of every possible complication, even if they don't know the complications exist or that these are well-known complications. And this is how I got to that document.
Q. Okay. And your reliance list actually reflects that you looked at that subsection, 109; right?

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A. Yes.
(Exhibit 3 marked for identification.)
BY MR. BENTLEY:
Q. Okay. I've just handed you what's been marked as Exhibit 3. And this is actually the entire --
A. Yes.
Q. -- CFR of that section.
A. Okay.
Q. And so you're testifying, today, that you reviewed this entire CFR, not being a regulatory expert, and honed in on, this is the applicable regulatory requirement for labeling; is that --
A. I did not read the whole thing.
Q. Okay, thank you.
MR. WALKER: Does that save you some time?
Q. Doctor, you've testified that you do not believe that that polypropylene and Prolene Soft mesh degrades over time; is that correct?
A. That's correct.
Q. Okay. And if you could turn your attention to page 27 in your report --
A. Right.
Q. -- to the section called -- entitled "Degradation and Particle Loss."

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And you begin, "There is no clinical significance to claims of alleged particle loss and mesh degradation over time."
So my question is, is there no degradation, or there's no clinical significance to the degradation that occurs?
A. It says there's no clinical significance.
Q. Okay. So degradation does occur, but you believe there's no clinical significance to it?
A. All the literature that I saw and I know -- and AUGS and SUFU have looked at this, and they feel that there's no clinical significance. I don't know if there's any real degradation, but I do know there's no clinical significance -- or my opinion is, no clinical significance.
(Exhibit 4 marked for identification.)
BY MR. BENTLEY:
Q. Okay. I'm going to hand you what's being marked as Exhibit 4. And this is an article from Arnaud Clavé, entitled "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants."
Do you see that?
A. Yes.

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Q. Okay. And are you familiar with this article?
A. I think I've looked at it sometime in the past, yes.
Q. Okay. I'll represent to you that it's, in fact, on your reliance list.
A. Yes.
Q. And, just briefly, if you'll turn your attention to page 265, in the top right.
A. Okay.
Q. You can see, there are pictures in two columns; and, on the left, it says "Intact," and on the right, it says "Degraded"?
A. Okay.
Q. Do you see that?
A. I do.
Q. Okay. And it appears those are zoomed-in photos, using scientific equipment to evaluate whether or not there's degradation, and they've listed those photos as "Degraded."
Do you see that?
A. I see that.
Q. Okay. And if you'll turn back to the front page of this article. You'll see the second sentence --

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or we'll read the conclusions.
It says, "This is the first study to evaluate synthetic implants using a vaginal approach for pelvic floor reinforcement. This study provides evidence contrary to published literature characterizing polypropylene (PP) as inert in such applications."
Did I read that correct?
A. Yes.
Q. Okay. So these authors in this article, Arnaud Clavé, that's on your reliance list, conclude that there's actually evidence of degradation; is that fair?
MR. WALKER: Object to form.
A. It says that they show, on these photos, degradation in patients who have had explanted polypropylene due to complications of the polypropylene, yes.
Q. Okay. And Prolift is made from a Prolene mesh, right; it uses a polypropylene?
A. Yes.
Q. And so what they're discussing is directly on point to the question here of whether or not degradation exists regarding polypropylene implants; is that correct?

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MR. WALKER: Object to form.
A. Not necessarily, because they didn't explant anybody who was not having a complication.
Q. Okay. So is it your opinion that complications are more likely to have degradation?
A. Possibly. But, again, I'm not a biomechanical whatever.
Q. Okay.
A. But --
Q. And if, in fact, the complications were tied to degradation, then there would be clinical significance; is that true?
A. Or, vice versa, the complication caused the degradation.
Q. Okay. So does this article impact your opinion that there's no clinical significance of degradation?
A. No.
Q. Based on the evidence in this article, would you agree that there is evidence of degradation in polypropylene implants?
A. This article suggests that, yes.
Q. Okay. And you don't have any reason to discount or critique this article, as you sit here

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today?
A. No, other than understand that it's from explanted complicated patients, yes -- no.
Q. And, in your report, you don't provide any reason or description of why you discounted this evidence; is that correct?
A. Because it was explanted complicated patients. That's why.
MR. BENTLEY: I'm going to move to strike as nonresponsive.
BY MR. BENTLEY:
Q. Doctor, in your report, do you provide any analysis or criticism of this article?
A. Yes.
Q. In your report, what page do you cite --
A. Oh. I don't -- no, I don't. In my opinion, I do.
Q. Okay. So let me just --
A. Okay.
Q. -- rephrase it.
A. Okay.
Q. In your report, you don't disclose any critique or analysis of why this article --
A. No.

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Q. -- demonstrating degradation --
A. Sorry.
Q. -- is not accurate?
A. No, I don't.
(Exhibit 5 marked for identification.)
BY MR. BENTLEY:
Q. Doctor, I'm going to hand you what's being marked as Exhibit 5. This is an article by Vladimir Iakovlev, entitled "Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients."
Do you see that?
A. I do.
Q. Are you familiar with this article?
A. Again, I think I've seen this. And it's probably on my reliance list, yes.
Q. And I'll represent to you that there's a number of articles on your reliance list from Iakovlev.
A. Yes.
Q. Okay. And, just briefly, if I could turn your attention to page 10.
A. Okay.
Q. There's a section entitled "Clinical significance of polypropylene degradation."

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Do you see that?
A. I do.
Q. Okay. And the authors in this article discuss a number of clinically significant events, such as, this second full paragraph, they start, "The clinical descriptions provided with the specimens indicated that in many cases mesh-related complications developed several years after mesh implantation."
Did I read that correct?
A. You did.
Q. And that's similar to what we've discussed earlier, that these complications can, in fact, occur many years after the implant; is that correct?
A. That's correct.
Q. Okay. Further down, they state, "As we showed, the degraded layer becomes thicker over time while its cracking indicated brittleness and loss of flexibility."
Did I read that correct?
A. Yes.
Q. Okay. In the last sentence in that paragraph, the authors state, "Degradation-related stiffening of the mesh is expected to increase over time."

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Did I read that correctly?
A. You did.
Q. And if the mesh became stiffer over time, that could have a clinical impact for the patient; isn't that correct?
MR. WALKER: Object to form.
A. Possibly, yes.
Q. Okay. And the next paragraph begins, "Another clinically important aspect of degradation is the potential for bacterial colonization of the fissures within the degraded material."
Did I read that correctly?
A. Yes.
Q. And, of course, that's another clinically -- a potential clinical impact from the degradation; is that correct?
A. Or from the reason the complication occurred, yes.
Q. Right. Which would be a clinically significant result; right?
A. Again, you're saying that the degradation occurred, caused the complication. And I'm saying, since this was a mesh that was explanted from somebody who had a complication, there might have been something

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that caused the complication, for the mesh to degrade.
Q. Could you give me examples, so I understand, of what complication it -- would happen to cause degradation?
A. If you have an exposed mesh and you get a severe infection and the infection is of a certain bacterial type, it could cause a problem with the mesh.
Q. Gotcha. And then, lastly, the next paragraph, second sentence, "The debris from prosthetic joints is well-known to cause tissue necrosis, inflammation and fibrosis around the joints. For polypropylene meshes, we observed occasional particles of degraded polypropylene in the surrounding tissue and macrophages."
A. Where are you again? I'm sorry.
Q. We're on the same page, on 10.
A. On 10. Same page. Right. Okay.
Q. We're looking at the --
A. 9, 10. Okay, got it --
Q. -- one, two, three -- fourth --
A. Yep.
Q. -- full paragraph --
A. Yeah.
Q. -- discussing the third clinical impact --

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A. Yes.
Q. -- potential impact of degradation --
A. I got it, um-hmm.
Q. -- second sentence. They're discussing the debris from the prosthetic joints is well known to cause tissue necrosis, inflammation and fibrosis around the joints.
That's talking about hip implants, I think. Is that fair?
A. I think, yes.
Q. Okay. But the next sentence, they state, "For polypropylene meshes, we observed occasional particles of degraded polypropylene in surrounding tissue and macrophages."
Did I read that correctly?
A. You did.
Q. Okay. So if the mesh is degrading and floating around, that -- these authors say that could be a clinical impact; is that correct?
MR. WALKER: Object to form.
A. They're not saying that. They're saying it was a clinical impact in joints. They observed occasional particles, but they don't really say there's a clinical impact.

Q. Right. But it's under their section entitled "Clinical significance of polypropylene degradation" --
A. I don't think you can assume that.
Q. I'm sorry. What's the section header title for that section --
A. "Clinical significance of polypropylene degradation." But they're talking about joints.
MR. BENTLEY: Move to strike from what they're talking about.
BY MR. BENTLEY:
Q. Doctor, if you could please turn to page 5 of your report, which is marked as Exhibit 1.
A. Okay.
Q. You're discussing your opinions and the bases for your opinions. And you say that one of the bases is from meetings and literature put out by AUGS and ACOG; is that correct?
A. That's correct.
Q. Okay. And I think, in your last deposition regarding the TVT-O, you actually, in fact, discuss one of those position statements from these organizations; isn't that correct?
A. That's correct.
Q. Okay. And you're familiar with the ACOG and

AUGS Position Statement No. 513, published in December of 2011, aren't you?
A. If you can show it to me and let me read it.
Q. I'll represent to you that this is on your reliance list.
A. I'm sure it is.
(Exhibit 6 marked for identification.)
BY MR. BENTLEY:
Q. We're marking this as Exhibit 6.
A. Yes.
Q. Okay. And you're familiar with this article; isn't that correct?
A. I am.
Q. In the abstract, ACOG and AUGS state, in their second sentence, "Based on the currently available limited data, although many patients undergoing mesh augmented vaginal repairs heal well without problems, there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh."
Did I read that correctly?
A. You did.
Q. Okay. So it seems like these organizations,

ACOG and AUGS, are talking about life-altering sequelae; isn't that correct?
A. That's correct.
Q. Okay. So the evidence does reflect there are life-altering complications from these devices; correct?
MR. WALKER: Object to form.
A. In their opinion, if they -- whatever they define as life-altering. But, yes, that is correct.
Q. Okay. And is one of your opinions for why you believe that Ethicon adequately warned of the complications associated with Prolift, because you feel that doctors already know all these complications?
MR. WALKER: Object to form.
A. I feel that surgeons that are performing pelvic organ prolapse surgery are aware of all these complications, yes.
Q. You would hope that they are; isn't that correct?
A. No, I would think they would be.
Q. Okay. If you could look at the first paragraph --
A. Um-hmm.
Q. -- third sentence, the ACOG and AUGS note that "Surgeons who perform those procedures may have

questions related to the FDA's notification."
Isn't that correct?
A. Correct.
Q. And that notification was in response to the complications of these devices; isn't that correct?
A. It was.
Q. And these organizations that you rely upon are stating that maybe doctors might need some more information; is that fair?
A. Yes.
Q. Okay. And this is like we discussed. You're well-positioned to be well-versed in the literature; right?
A. Um-hmm.
Q. And some doctors might --
A. I hope.
Q. -- might not be as well-versed in the literature; right?
MR. WALKER: Object to form.
A. Possibly, yes.
Q. And that's what these organizations right here are noting, is that some doctors would like some more information; right?
MR. WALKER: Object to form.

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A. Right.
Q. If you could turn to page 2. You can see, under the section titled "What outcome data exists for vaginal placement of synthetic mesh for pelvic organ prolapse," the second paragraph, the last sentence, they say, "Although the risk of mesh erosion varied, it was a risk that did not exist for native tissue repairs."
You would agree with that; right?
A. No, I would not --
Q. You think --
A. -- agree with that.
Q. -- the risk of mesh erosion existed for native tissue repair?
A. I would say, risk of synthetic material during native tissue repair can occur.
Q. Just to be clear, you're saying that the risk of mesh erosion exists with native tissue repair?
A. In some native tissue repairs, yes.
Q. So you dis --
A. Not mesh, but synthetic material.
Q. I don't understand. I'm sorry.
A. Okay.
Q. Let me rephrase.
A. Okay.

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Q. So the last sentence of this section states, "Although the risk of mesh erosion varied, it was a risk that did not exist for native tissue repairs."
My question for you, Doctor: Do you agree with AUGS' and ACOG's statement right there?
A. Well, if you don't use mesh, then there's no risk for mesh -- whatever you're talking about -- for mesh erosion.
Q. So you agree with their statement?
A. Yes.
Q. Okay.
A. Yes.
Q. Thank you.
And in the next paragraph, the last sentence, they state, "In this review, the rate of reoperation to correct complications, as well as the total reoperation rate, was highest for vaginal mesh kits compared with vaginal native tissue and abdominal repairs, despite shorter overall follow-up."
Did I read that correctly?
A. Yes.
Q. Okay. And you would agree with that, wouldn't you?
A. You'd have to quantify that.

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Q. Well, the quantity is, the rate of total reoperation rate, they're saying, is higher for mesh-based repairs --
A. How do you quantify "reoperation," though? That's the question. If somebody has a small piece of mesh removed from her vagina in the office, is that a reoperation? Right?
Q. Right. If they're doing --
A. Or does she go to the OR?
Q. I'm sorry. So are you disagreeing or agreeing with ACOG and AUGS' statement, as presented to you?
A. I know the study they're quoting. It's the Diwadkar study. And, yes, if you look at all the reasons why the mesh was removed, then, yes, there were more reoperations, if you consider an office procedure a reoperation. Yes.
Q. So you agree with this statement --
A. Yes.
Q. -- here? Okay. Thank you.
A. Yes.
Q. Doctor, if you could turn your attention to page 3.
A. Okay.

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Q. On the left column, at the bottom of the page, these committees are discussing that "Pelvic pain, groin pain, and dyspareunia can occur with pelvic reconstructive surgery regardless of the use or nonuse of mesh."
And that's your position; right?
A. That's correct.
Q. Okay. And they continue, though, "However, a complication unique to mesh is erosion (also described as exposure extrusion), which seems to be the most common complication, and may sometimes present several years after the index procedure."
You would agree with that; right?
A. I do.
Q. Okay. And they continue there, "Increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction or shrinkage) that result in taut sections of mesh."
Did I read that correctly?
A. You did.
Q. And that's what we were previously discussing, that, in fact, mesh can contract; isn't that correct?
A. That's what they say, yes.

Q. And do you disagree with that?
A. I do.
Q. Okay. And anywhere in your report, do you discuss your disagreement with this position statement?
A. With this position statement, itself?
Q. Yes.
A. No. I just --
Q. Anywhere in your report, do you discuss why you think that the medical literature evidencing mesh contraction, as referenced in ACOG and AUGS' statement right here -- do you discuss, anywhere in your report, that mesh contraction doesn't exist?
A. Well, let's see.
MR. WALKER: If I could point the doctor in the right direction?
MR. BENTLEY: Sure.
MR. WALKER: Page 27.
THE WITNESS: Okay. Um-hmm.
MR. WALKER: I think, in that first full paragraph, Doctor.
BY MR. BENTLEY:
Q. Doctor, counsel has directed your attention to page --
A. Yes.

Q. -- 27, the first --
A. Right.
Q. -- full paragraph.
A. Right.
Q. And my question was: Anywhere in your report, do you discuss your disagreement with the existence of mesh contraction, as evidenced in this position statement by AUGS and ACOG?
A. This paragraph addresses that. But I don't specifically address this para -- this AUGS statement --
Q. Can you please --
A. -- this --
Q. -- direct your attention to where you discuss that mesh contraction doesn't exist?
A. Okay.
Q. Well, counsel can probably revisit that on redirect.
As you sit here today, can you explain to me why you disagree with ACOG's --
A. Because I don't think the mesh contracts. I think the tissue around the mesh contracts.
Q. Resulting in shrinkage?
A. No. Shrinkage would mean that the mesh actually changes, goes from 6 centimeters to

3 centimeters. And it doesn't, it stays the same --
Q. Okay. If you can --
A. -- by contracture --
Q. -- draw your attention down to the next paragraph.
A. Okay.
Q. You'll see, at the end of that paragraph, "One ultrasound study evaluating women at three months after anterior vaginal mesh placement" --
A. Um-hmm.
Q. -- "found severe contraction or shrinkage defined as a decrease of more than 50 percent of the size of the mesh in 9.3 percent of patients."
Would that count as shrinkage to you, a reduction of 50 percent of the mesh?
A. At three months, it would count as shrinkage. But there are other studies that have followed them out later, that did not show shrinkage. And I would assume this shrinkage was due to implantation technique.
MR. BENTLEY: Move to strike after the nonresponsive answer.
BY MR. BENTLEY:
Q. In the next paragraph, they continue, "Based on the currently available limited data, although many

patients who undergo mesh augmented vaginal repairs heal well without problems, there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh."
Did I read that correctly?
A. You did.
Q. And again, this is another piece of medical literature that you relied upon; correct?
A. That's correct.
Q. That's evidencing life-altering problems with these products; isn't that correct?
MR. WALKER: Object to form.
A. That's correct.
Q. Okay. You simply disagree with their statement?
A. I disagree.
Q. Okay. And in your report, you don't discuss your disagreement with that statement from ACOG and AUGS; correct?
A. No.
Q. Okay. As you sit here today, can you explain why you don't believe that there's life-altering problems with these complications --

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A. Because I --
Q. -- as evidenced by this position statement?
A. Because I've seen these patients and I've seen them over and over and over again; and you can -- they can get treated; and there are many patients that don't have life-altering. So it depends on how you define "life-altering."
Q. Okay. So just based on your personal experience treating women, you haven't seen it, so that's why you disagree with the medical literature?
A. No. Based on my education, training, and experience, yes.
Q. But the rest of your opinions in your report are based upon the medical literature; correct?
A. And my education, experience, and training.
Q. Right. But you can't, as you sit here today, provide any reason as to why you disagree with medical literature that you rely upon, other than your personal experience, including your training and experience and education?
A. This isn't medical literature. This is a committee opinion. It's not medical literature. Medical literature is a meta-analysis, randomized control trial, prospective cohort, retrospective cohort.

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The list goes on. This is a committee opinion.
Q. And in your last deposition, you actually relied upon a committee opinion from these very organizations; isn't that correct?
A. I relied on a statement -- position statement. That's different than a committee opinion.
Q. And this committee opinion's actually a review of the medical literature; isn't that correct?
A. In 2004.
Q. Do you want to read the front page to correct your date?
A. It says since 2004. Oh, I'm sorry, 2011. Okay. My --
Q. Right. And this is a review --
A. My mistake.
Q. -- of the medical literature --
A. Correct.
Q. -- about up to the point when Prolift was withdrawn; isn't that correct?
A. Well, let's see.
(Off-the-record comments between Mr. Bentley and the court reporter.)
BY MR. BENTLEY:
Q. Withdraw.

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Doctor, as you sit here today, can you please explain why you're discounting the conclusions of ACOG and AUGS, regarding the existence of evidence demonstrating life-altering complications associated with these products?
A. Because, in looking at their references that they looked at, there are many other references that contradict what they're saying.
Q. What references are you referring to that state there's no existence of life-altering complications related to these products?
A. I don't know if there's a definition of "life-altering." So we can go back to that, but...
Q. But this statement uses that terminology; correct?
A. This statement uses that terminology --
Q. And you indicate --
A. -- in their --
Q. -- in your report that these statements and these organizations are important to your opinions; correct?
A. They are.
Q. Okay. Doctor, is one of the reasons that you feel that the risk-benefit profile for Prolift is

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beneficial is because you feel that native tissue repairs weren't as efficacious as the Prolift?
A. In some people's hands, yes.
Q. And is that based upon some earlier evidence, that native tissue repair wasn't as efficacious --
A. Yes.
Q. -- as hopeful?
And, in fact, you discuss that information in your report; isn't that correct?
A. I do.
Q. Okay. And are you aware that some scientists went back and reevaluated that data and, in fact, found native tissue repair was more efficacious than previously thought?
MR. WALKER: Object to form.
A. That's not necessarily correct. But, yes --
Q. Are you aware that --
A. -- they did -- I am aware that they went back and looked at objective data and subjective data --
Q. And they found that native --
A. -- and they quantified it. It doesn't necessarily mean that it's any better. It just means that if the patient had a native tissue repair and she had a recurrence of her prolapse, but it didn't bother

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her, then they considered that a positive result and that she didn't need a reoperation. That's what that study was about.

Q. If you could please turn your attention to page 4 of this committee opinion reviewing the medical literature regarding --

A. Okay.

Q. -- this product. You can see, on the top left, it states, "A 2001 randomized trial of three methods of anterior wall repair, including native tissue, ultralateral anterior colporrhaphy, and absorbable vaginal mesh, reported success rates (based on anatomic success definitions) of only 30 to 46 percent"?

A. Correct.

Q. And they have a citation that says "Study No. 22," which is the Weber --

A. The Weber study.

Q. -- study, 2001.

A. That's correct.

Q. And you actually cite to the Weber study in your report --

A. I do.

Q. -- on page 10?

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A. I do.

Q. And then the authors of ACOG and AUGS go on to continue that "These low success rates were frequently cited as a reason why innovations such as vaginal mesh were needed to decrease failure rates."

And we just discussed that; correct?

A. Correct.

Q. Okay. And they continue, "The original data from this study were recently reanalyzed using modern outcome measures (a composite of anatomic outcomes and subjective success), and the revised success rates for the three arms of this RCT" -- randomized control trial -- "were comparable, with 89 percent of women having no objective prolapse beyond the hymen."

Did I read that correctly?

A. You did.

Q. And would you agree then an 89 percent success rate is pretty good?

MR. WALKER: Object to form.

A. In the hands of one surgeon, yes.

Q. Okay. But the Weber study was using a database that wasn't just one surgeon; isn't that correct?

A. It was -- no, it was a group of surgeons at the Cleveland Clinic, I think. But --

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Q. Right. Not just one surgeon; right?

A. Well, but you can't -- you can't extrapolate that to the general population. Native tissue repairs are all done differently. If I do a native tissue repair and you do a native tissue repair, if you're a pelvic floor surgeon, we're going to do it differently.

Q. Okay.

A. Okay? So there's no standardization of native tissue repairs.

Q. If you can draw your attention to the next section, Doctor --

A. Um-hmm.

Q. -- entitled "Who are the best patients for transvaginally placed mesh?" Second sentence, "Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment)" -- which we discussed; correct?

A. Correct.

Q. "...or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures."

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Would you agree with that, also?

A. I would agree with that.

Q. Okay. So you would agree with the author's statement here, that mesh kits such as Prolift should be reserved for high-risk patients?

A. I do.

Q. Okay. Doctor, are you aware that Anne Weber, the author of these original native tissue repair studies, has actually written reports in this very litigation?

MR. WALKER: Object to form.

A. For the plaintiff?

Q. Yes.

A. Yes.

Q. Have you read her reports?

A. I skimmed it.

Q. Are you aware that her reports discussing this very issue are contrary to your opinions, using her very data?

A. Yes.

Q. That doesn't impact your opinion?

A. Yes.

Q. It does impact your opinions?

A. Oh, no. No, I'm sorry, it doesn't. But I'm

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aware that it's different than hers --
Q. Okay.
A. -- yes.
Q. If you could turn to the page in your report -- to page 11 of Exhibit 1.
A. Oh.
Q. You had previously stated that you don't believe that the ACOG AUGS position statement is helpful evidence or reliable evidence; is that correct?
MR. WALKER: Object to form.
MR. BENTLEY: Strike that.
BY MR. BENTLEY:
Q. Doctor --
A. Are you talk --
Q. -- how would you characterize the AUGS position statement -- or the AUGS position statement, in the levels of evidence?
Was it important enough to include in your report?
A. Yes.
Q. Okay. But they had some conclusions that were contrary to your opinions here; isn't that correct?
A. Are you talking about the AUGS position --
Q. Yes.

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A. -- or are you talking about the ACOG committee report? You said the AUGS position. I'm a --
Q. Well, it's AUGS --
A. -- little confused.
Q. -- it's -- let me re-ask.
A. But that's an ACOG committee bulletin. So it's from ACOG. AUGS might have had some, you know, effect in drafting it --
Q. Right.
A. -- but it's an ACOG, it's not an AUGS --
Q. That's fair.
A. -- position statement.
Q. I appreciate that.
A. That's fine. So you're referring to this one?
Q. Yes, sir.
A. Okay.
Q. So let me rephrase that. I'm sorry.
A. Okay.
Q. Was the ACOG 2011 committee opinion that we just reviewed, dated December 2011, important enough for you to include in your report?
A. It was.
Q. Okay. But the authors had some contrary

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conclusions to your opinions here; correct?
A. That's correct.
Q. Okay. Doctor, on your report, on page 11, you begin discussing the evidence regarding Gynemesh PS, starting in 2002. Do you see that?
A. On page 11 of my report?
Q. Yes.
A. Yes.
Q. Okay.
A. Okay.
Q. And then on the next page, you cite to a number of studies, including the Nilsson 2013 study.
Do you see that?
A. Yes, I do.
Q. Okay. And that's a study regarding the TVT mesh; right?
A. That's correct.
Q. Okay. And then you cite to the Ford Cochrane Review, also --
A. Um-hmm.
Q. -- 2015?
And that's also another --
A. Right.
Q. -- study regarding the TVTs; right?

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A. Yes.
Q. Okay. Or midurethral slings; right?
A. Midurethral, right.
Q. And then, in the next paragraph, you cite to a number of studies, all published before the Prolift was available; isn't that correct?
A. That's correct.
Q. Okay. And then turning the page, turning to page 14, you begin discussing some of the Prolift data; is that correct?
A. That's correct.
Q. And then, on page 15, your first full paragraph states, "According to the latest Cochrane Review," and you cite Maher 2013.
Do you see that?
A. Yes.
Q. And that's not a correct statement; isn't that correct? That was a horrible question.
Now, on page 15, you start out, "According to the latest Cochrane Review Maher 2013..."
A. Right.
Q. That's not correct. There's a more recent Cochrane Review regarding mesh kits to treat prolapse; isn't that correct?

A. I'm not aware of it, if it is. If I cited it...
Q. If you could turn your attention to page 18.
A. Right.
Q. On the bottom of the page, you discuss, "In the most recent Cochrane Review Maher 2016."
Do you see that?
A. Ah, okay.
Q. So --
A. Yes.
Q. -- your discussion on page 15 is not actually of the latest Cochrane Review --
A. That's correct.
Q. -- isn't that correct?
A. That's correct. And it might be a type error, I think. A typing error. It should be --
Q. But if --
A. But if it -- yeah.
Q. If the data on page 15 is, in fact, from the Maher 2013 Cochrane Review, that's actually outdated, now, by the new 2016 Maher; isn't that correct?
A. That's correct.
Q. Okay. And so you would like to update that, maybe, to include the actual updated, most recent

Cochrane Review that includes all of the current evidence; isn't that correct?
A. That's correct.
(Exhibit 7 marked for identification.)
BY MR. BENTLEY:
Q. Okay. And I'm going to hand you what's being marked as Exhibit 7, which is the 2016 Maher Cochrane Review.
A. Okay.
Q. Now, on page 18 of your report, you discuss a number of findings from the 2016 Maher Review; isn't that correct?
A. Yes.
Q. Okay. And let's look at Exhibit 7, that we just marked, which is the Maher Cochrane Review.
If you could turn to page 2.
A. Now, wait a minute. Can you go back? What did you say on the last one?
Q. I was referencing --
A. The Maher -- on page 16.
Q. On page 8 -- well --
A. Oh.
Q. -- we agreed that page 15 is not --
A. Yes, yes.

Q. -- the most recent --
A. You said on page 16. I'm sorry.
MR. WALKER: 18.
A. 18? Okay.
Q. Page 18 --
A. Gotcha.
Q. -- you discussed --
A. Gotcha.
Q. The --
A. Yes.
Q. And you provide a couple of --
A. Right.
Q. -- findings from --
A. No, no, I thought we were on page 16. I --
Q. Okay. And --
A. -- wasn't looking. Okay.
Q. -- the findings you discuss in your report --
A. Um-hmm, yes.
Q. Well, let's look at the review.
So, on Exhibit 7, page 2 --
A. Okay.
Q. -- under "Authors' Conclusions" --
A. Yes.
Q. -- they begin, "While transvaginal permanent

mesh is associated with lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination than native tissue repair, it is also associated with higher rates of reoperation for prolapse or stress urinary incontinence or mesh exposure and higher rates of bladder injury at surgery and de novo stress urinary incontinence."
Did I read that correctly?
A. You did.
Q. Okay. And we've discussed some studies that found that similar finding, that there's a higher reoperation rate if you include all of these different surgical procedures that might happen after a Prolift implant; isn't that correct?
A. Correct.
Q. Okay. And they continue, "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery."
Did I read that correctly?
A. You did.
Q. And, Doctor, you would agree with that, because you've previously testified that you think Prolift is appropriate for some patients, but not necessarily for all patients; isn't that correct?

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MR. WALKER: Object to form.
A. That's correct.
Q. And they continue, "While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position."
Did I read that correctly?
A. Yes.
Q. Now, you disagree with that sentence from these authors; correct?
A. Correct.
Q. And nowhere in your report do you provide an analysis or criticism of why you disagree with this conclusion; isn't that correct?
A. No. But I think I support -- show other data that contradicts that.
Q. Okay.
A. Okay?
Q. If you could please turn your attention to the next page. Under the section "Key Results" --
A. Yes.
Q. -- the first paragraph, the second-to-last sentence, they state, "If the reoperation rate for prolapse urinary incontinence or mesh exposure after

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native tissue repair is assumed to be 5 percent, the risk would be between 7 percent and 8 [sic] percent after permanent mesh repair."
Did I read that correct?
A. 7 and 18 percent.
Q. Right. So they're saying that mesh kits, like Prolift, have a higher reoperation rate --
A. After permanent mesh repair.
MR. WALKER: Object to form.
Q. Is that correct?
A. That's correct. That's what it says.
Q. Do you agree with that finding?
A. Well, I don't agree with the fact that you can assume reoperation rate with the native tissue repair is 5 percent.
Q. I appreciate that. But my question is: Do you have any criticism or critique of their analysis, in reviewing all of this medical literature that reach this conclusion that --
A. No.
Q. -- we just read?
A. No.
Q. So you feel okay, assuming that they did their calculations right, they looked at the evidence

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correctly, and this is what the data shows; is that fair?
A. Correct.
MR. WALKER: Object to form.
Q. And then they continue, "Eight percent of women in the mesh groups required repeat surgery for mesh exposure."
Is that correct?
A. Where is that?
Q. Very last sentence. I'm sorry. They conclude that paragraph, "Eight percent" --
A. Oh, yeah, it's written out. I'm looking for an "8." Okay, I gotcha.
Q. Did I read that correctly?
A. Yes, you did.
Q. Okay. And again, you don't have any criticisms of them reaching that finding based off the data they looked at; right?
A. No.
Q. And this is, as we discussed, one of the Level 1 evidence, a systematic review; correct?
A. Correct.
Q. This is the highest evidence you can get; correct?

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The Cochrane Review group's very reputable; correct?
A. Yes.
Q. And, in fact, you rely upon this group; correct?
A. Right.
Q. And they looked at all the data and came to these conclusions based off that data; isn't that correct?
A. That's correct.
Q. And they have findings. And you agree with their findings, you just disagree with their conclusions; correct?
A. Correct.
Q. Okay. And nowhere in your report do you provide an analysis of why you disagree with their conclusions, other than you cite to some other evidence?
A. Correct.
Q. And, lastly, if you could turn your attention to page 16, please.
A. Of my report or --
Q. I'm sorry, of the Cochrane --
A. Cochrane?
Q. Sorry.

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A. Okay.
Q. On 16, under Section 1.4.2...
A. Got it.
Q. On page 16, the authors of the Cochrane Review have a section entitled "1.4.2 mesh Exposure."
A. Okay.
Q. And, here, they're looking at 19 RCTs, one to three-year review. Do you see that?
A. Yes.
Q. And we discussed, the RCTs are also in the highest level of evidence; correct?
A. They are.
Q. And they looked at 19 of them. And they state, "While a woman undergoing a native tissue repair has no risk of mesh exposure, overall, 134 out of 1,097, or 12 percent, women in the transvaginal permanent mesh groups had mesh exposure."
Did I read that correctly?
A. Yes, you did.
Q. Okay. And they're just stating that after they looked at 19 RTCs, they found that 12 percent of the women had exposure; correct?
A. Correct.
Q. Okay. And then, as we were discussing

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earlier, down in Section 1.4.4 on that same page, they state that "Surgery for mesh exposure was required in 8 percent of women, 100 out of 1227."
Did I read that correctly?
A. Yes.
Q. Okay. And so of the, you know, 12 percent of women that had erosion, 8 percent of all of the women, overall, had to have surgery for that erosion; correct?
A. Correct.
MR. WALKER: I'm sorry, counselor, where was the 8 percent?
MR. BENTLEY: At the bottom of the page on 16, under 1.4.4.
MR. WALKER: Got it. Thanks.
BY MR. BENTLEY:
Q. So, well over half of the women that had the erosion had to have some sort of surgical revision procedure to treat their --
A. Correct.
Q. And that's consistent with your review of the medical literature; correct?
A. Correct.
Q. And you don't have any reason to doubt the findings of the Cochrane Review, do you?

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A. I do not.
Q. Okay. Doctor, if you could turn back to Exhibit 1, your report. On page 19 --
A. Okay.
Q. -- you have a section entitled "Mesh Exposure." Do you see that?
A. Yes.
Q. Okay. And you start, "An overall mesh explosive rate of 3 to 8 percent is an acceptable rate by today's standards."
Did I read that correctly?
A. Yes, you did.
Q. And we just looked at the Cochrane Review that found at least a 50 percent higher exposure rate; correct?
A. Correct.
Q. What is your standard for determining what's an acceptable rate of erosion?
A. Just the medical literature and my experience and education.
Q. Okay. And the Cochrane Review from 2016, from this year, actually found at least a 50 percent higher rate; isn't that correct?
A. That's correct.

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Q. Okay. So would you like to update your report, where you said that 3 to 8 percent is acceptable?
A. No, I don't go -- I'm not just looking at the Cochrane; I'm looking at everything. And most of the randomized trials and most of the experts in the field think that a 3 to 8 percent is acceptable in today's standards.
Q. So, if it was well above that, would it be unacceptable?
A. It would be above the standard.
Q. Okay. So if, in fact, the exposure rate was 12 percent, that would be above the standard by today's standards?
A. I would think so, yes.
Q. Okay. And the Cochrane Review actually looked at 19 RCTs; correct?
A. Correct.
Q. Okay. Doctor, if you could turn to page 21 in your report. We briefly looked at this earlier, but I forgot to ask.
A. Okay.
Q. Your section's entitled "Adequacy of company IFU in patient brochures."

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Do you see that?
A. Yes, I do.
Q. Did you look at any patient brochures?
A. I've seen them, yes.
Q. Okay. But in your report, do you discuss any of their brochures or why you feel they're adequate?
A. Patient brochures?
Q. Yes.
A. I didn't discuss them, no. But I've used them with patients.
Q. Okay.
A. And so I know of them and I've seen them. And we used to used them in the courses.
Q. Okay. But you don't present or disclose any opinions regarding the patient brochures in your report; correct?
A. Other than my experience with them has been they're adequate.
Q. Sure. But in your report, you don't have a single sentence discussing patient brochures, correct, other than that section header?
A. No. No. No. Correct.
Q. And like the legal regulatory requirements for the IFUs, you haven't reviewed those same

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requirements for patient labeling; correct?
MR. WALKER: Object to form.
A. No. I didn't even know there was regulation for patient labeling.
Q. And have you reviewed the Ethicon internal standards for patient labeling?
A. I have not.
Q. Okay. And have you reviewed Ethicon's internal standards for what needs to go into an IFU?
A. No.
Q. Okay. Doctor, do you have an understanding of whether or not the mesh in the Prolift elicits a foreign-body reaction in the body?
A. It does.
Q. Okay. And does that continue for as long as the implant is inside the woman's body?
A. I don't think so, no.
Q. You think the foreign-body reaction, at some point, stops?
A. It ends at about six to eight weeks.
Q. Okay. And what evidence are you relying upon for that opinion?
A. Some explanted evidence that was done in rats, I think.

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Q. And what study is that?
A. It's a study that -- I think it was quoted with -- what's his name -- I can't remember. I do have a study. I don't know which one it is, but I do have a study that gives you the reaction to mesh from implantation to six to eight weeks, and at that point it shows no foreign-body reaction.
Q. So you haven't reviewed any documents from Ethicon scientists discussing the existence of a chronic and ongoing foreign-body reaction related --
A. No.
Q. -- to polypropylene implants?
A. No.
MR. WALKER: Object to form.
Q. Would you have liked to have seen those documents, if they exist?
A. In the context of whatever they were discussing.
Q. Right.
A. Yeah.
Q. And would you agree that the foreign-body reaction and the inflammatory processes that occurred -- those can lead to scarring and scar plating?
MR. WALKER: Object to form.

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A. That can, yes.
Q. Do you have an understanding that the foreign-body reaction, leading into the scar plating, can lead to pain for a woman?
MR. WALKER: Object to form.
A. I don't think the scar plating is the cause of pain, no.
Q. Okay. Do you know whether the amount of mesh implanted impacts the intensity of the foreign-body reaction?
A. Well, the more mesh, the more foreign-body reaction, yes.
Q. So you would agree that with a bigger piece of mesh, there's more foreign body reaction?
A. Yes.
Q. Which could potentially lead to more scar plating; correct?
MR. WALKER: Object to form.
A. Yes.
Q. Doctor, are you familiar with bridging fibrosis?
A. I am not.
Q. You haven't reviewed any of the medical literature regarding bridging fibrosis in mesh implants?

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A. I haven't seen anything specific to bridging fibrosis.
Q. And you haven't reviewed any of Ethicon's internal documents discussing bridging fibrosis and the Prolift implant?
A. No.
Q. Doctor, if you could please turn to page 18 of your report.
A. Do you mind if I stand while I talk to you?
Q. Sure.
A. Are you sure?
Q. No video.
A. What's that?
Q. If you turn to 18 --
A. I got it, yeah.
Q. -- in your report.
A. Okay.
Q. Your first full paragraph, you state, "Medical societies (ACOG, AUGS, SUFU, AUA, SGS) have all put four favorable position statements in regards to mesh used in pelvic organ prolapse." Is that correct?
A. Correct.
Q. Okay. And we just looked at a committee opinion by ACOG. Do you remember that?

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A. Yes.
Q. Okay. And it was critical of using these mesh-based kits such as Prolift; correct?
A. Correct.
Q. Okay. So that opinion in your report isn't entirely accurate; isn't that correct?
A. That's correct.
Q. Doctor, if you could please turn your attention to page 20 in your report.
A. Okay.
Q. In that first paragraph, halfway through, you state, "It's common knowledge for pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse, with or without the use of mesh, can potentially cause complications that can be temporary or permanent, including, but not limited to, pelvic pain, dyspareunia, or pain with sexual intercourse, scarring, vaginal narrowing, leg/groin pain, urinary retention, and other voiding problems."
Did I read that correctly?
A. You did.
Q. Okay. And what's your basis for opining as to what the common knowledge is of all pelvic floor surgeons?

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MR. WALKER: Object to form.
A. Because pelvic floor surgeons learn from training, from working with other pelvic floor surgeons, from their experience, the medical literature, and their experience with their patients. And these are all complications that can occur with any type of pelvic organ prolapse.
Q. Okay. So you're not citing to any specific study reviewing the general knowledge of surgeons; is that fair?
A. No.
Q. Okay. And you haven't --
A. That's correct.
Q. And you haven't undertaken any type of effort to poll or take a survey of the other doctors; correct?
A. No.
Q. And we discussed that some surgeons have less access to medical literature than you do; correct?
MR. WALKER: Object to form.
A. Maybe not less access, but knowledge of medical literature.
Q. Okay.
A. Okay?
Q. And so it would be fair to say that maybe

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some doctors don't have the same level of knowledge as you might; isn't that fair?
MR. WALKER: Object to form.
A. That's correct.
Q. Would you agree that Ethicon has access to the best information regarding the frequency and severity of complications related to its devices?
MR. WALKER: Object to form.
A. Not necessarily.
Q. Would you agree that Ethicon has access to all the medical literature that you might have access to?
A. Yes.
Q. And Ethicon also has access to internal data; is that correct?
A. That's correct.
Q. And Ethicon has access to adverse events that are reported to its company from doctors like you; correct?
A. Correct.
Q. Okay. So Ethicon has access to a wealth of information regarding the complications of its devices; correct?
MR. WALKER: Object to form.

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A. Correct.
Q. Would you agree that it would be reasonable for a company like Ethicon to share that information with doctors, in case they don't have your level of knowledge regarding the complications of these devices?
MR. WALKER: Object to form.
A. They did. I think they did.
MR. BENTLEY: I'm sorry, I'm going to move to strike.
THE WITNESS: Okay.
BY MR. BENTLEY:
Q. That wasn't exactly my question, though.
A. Oh.
Q. Doctor, would you agree that it would be reasonable for a company like Ethicon to share that information with doctors, in case those doctors don't have your level of knowledge regarding the complications of devices like Prolift?
Would you agree that that would be reasonable, for Ethicon to share that information?
MR. WALKER: Object to form.
A. Yes.
Q. Would you agree that it would be reasonable for Ethicon to share that information with doctors via

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the IFU or via a dear-healthcare-provider letter?
MR. WALKER: Object to form.
Q. Would that be reasonable?
A. I don't think they need to put it in the IFU.
MR. BENTLEY: Sorry, I move to strike as nonresponsive. Let me re-ask the question.
BY MR. BENTLEY:
Q. Would you agree that it would be reasonable for a company like Ethicon to share that information via the IFU or a dear-healthcare-provider, or some other way to get the information out to doctors, in case not all doctors had access to the information such as you?
MR. WALKER: Object to form.
Q. Would that be reasonable?
A. Yes.
Q. Okay. And, ultimately, that information regarding the complications, that's important to patients because that involves safety; isn't that correct?
A. That's correct.
Q. And that's important for the informed consent for the patient to make an informed decision, so they know what the risks are and what the true risks or complications regarding the device is, before they

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choose to undergo a procedure to have one of these devices permanently implanted; isn't that correct?
MR. WALKER: Object to form.
A. Correct.
Q. And if patients don't have that information, they can't make an informed consent; isn't that correct?
MR. WALKER: Object to form.
A. That's correct.
Q. Doctor, you offer opinions as to the adequacy of the warnings provided by Ethicon; isn't that correct?
A. That's correct.
Q. And you've reviewed the IFUs; isn't that correct?
A. That's correct.
Q. Do you understand that there's been multiple drafts of IFUs for the Prolift devices?
A. I do.
Q. Do you know what --
MR. WALKER: Object to form.
I'm sorry. Drafts, are you referring to actual IFUs or drafts of --
MR. BENTLEY: I'll clear that.
BY MR. BENTLEY:
Q. Doctor, do you understand that there's been

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multiple versions or iterations of final Prolift IFUs that Ethicon's released? Do you understand that there's been multiple versions of it?
A. Yes.
Q. And do you know which versions of the IFU you've reviewed to reach your --
A. At one time or another --
Q. -- opinions in this case?
A. -- I've reviewed all of them.
Q. Okay. And so is your opinion that all of the IFUs adequately warn doctors?
A. I think the earlier IFUs had less warnings than the later IFUs.
Q. And, ultimately, Ethicon decided to add more warning information; is that correct?
A. That's correct.
Q. And you would agree, that was reasonable?
A. I would agree that was reasonable, yes.
Q. And that could be helpful for patient safety; correct?
MR. WALKER: Object to form.
A. Yes.
Q. Okay. And if Ethicon actually had the information available when it first put out the Prolift

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IFU, regarding those complications and safety information -- if Ethicon had that information from the very beginning, should Ethicon have put that information in the IFU from the very beginning?

MR. WALKER: Object to form.

A. Any information that they had that was scientific, yes.

Q. Okay. So let me clean that up.

A. Okay.

Q. Through time, Ethicon released a number of updated Prolift IFUs; correct?

A. That's correct.

Q. And we've discussed that, ultimately, Ethicon added more information regarding those warnings into the IFU; correct?

A. That's correct.

Q. And if Ethicon had had the information regarding those complications and that safety data from the very beginning, would you agree that Ethicon should have put that information in the very first IFU?

MR. WALKER: Object to form.

A. If they had the information, yes.

Q. Doctor, do you think it's helpful for doctors if information regarding the appropriate patient for the

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Prolift procedure had been conveyed to them from Ethicon?

MR. WALKER: Object to form.

A. Patient selection? No.

Q. Bad question.

We discussed, today, that you don't believe that the Prolift device is the appropriate device for every patient for a primary surgery; correct?

MR. WALKER: Object to form.

A. That's correct.

Q. If Ethicon also had that same belief, that the Prolift was not appropriate for every patient suffering from prolapse, do you think it would have been helpful for Ethicon to get that information out to doctors?

MR. WALKER: Object to form.

A. Yes .

Q. Do you know, as you sit here today, whether or not Ethicon internally believed that Prolift was not appropriate for all patients?

A. Yes.

Q. What's your understanding as to Ethicon's position on the appropriateness of the Prolift device for patients?

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A. Patients who were high risk, for patients who are high risk for failure or recurrences, or advanced prolapse patients or patients who were, from a physical standpoint, a native tissue repair, and a large open repair would be detrimental to their health. Just clinical aspects like that. Yes.

Q. It's your testimony that that was Ethicon's understanding of who the appropriate patient was for Prolift; is that correct?

A. That --

MR. WALKER: Object to form.

A. Yes, that's my understanding.

Q. And you agree that that information should have been put out there by Ethicon; correct?

MR. WALKER: Object to form.

A. It was.

Q. I'm sorry. I'm just striking out.

A. Well, you asked me.

Q. Sorry.

A. Because I was the one that put it out. When I give these courses, that's what I told the doctors. So it was out there.

Q. Appreciate that.

A. I appreciate that.

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Q. I'm going to re-ask.

A. Okay.

Q. Can you agree that it would have been reasonable for Ethicon to put that information out there to doctors, regarding which patients the Prolift was appropriate for?

A. Yes.

Q. Yes. Okay.

A. Okay.

MR. BENTLEY: Doctor, thank you. That's all the questions I have.

EXAMINATION

BY MR. WALKER:

Q. Doctor, let's begin --

A. Let's do it.

Q. -- where we ended.

A. Yes, redirect.

Q. All right.

A. Famous words.

Q. Doctor, I direct your attention to page 21 of your report.

THE WITNESS: Do they get -- do you get to keep my articles that I brought?

THE REPORTER: I do. I will give you the

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originals back when I finalize --
THE WITNESS: Oh, okay.
BY MR. WALKER:
Q. I direct your attention to page 21 --
A. Okay.
Q. -- of your report.
A. Got it.
Q. Specifically, the last paragraph.
A. Um-hmm.
Q. Doctor, you opine, in your report, that the Prolift IFU, in addition to other materials, adequately describes the risks that are specifically unique to Prolift; is that correct?
MR. BENTLEY: Objection.
A. That's correct.
Q. And, Doctor, what is the basis for your opinion that the Prolift IFU adequately describes the risks that are specific or unique to Prolift?
MR. BENTLEY: Objection.
A. Based on the possible risks associated with Prolift, itself, I think they elicit them correctly. And based on the fact that any other pelvic organ prolapse can have other risks, and they don't have to list those if -- it should be common knowledge with

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pelvic floor surgeons, which I think it is.
Q. And are your reasons for thinking that fleshed out on page 22 of your report?
A. It is.
MR. BENTLEY: Objection.
Q. One of the documents that you mention on page 21 is the Surgeon's Resource Monograph for Prolift; correct?
A. That's correct.
MR. WALKER: I'd like to mark that. I'm going to mark this as Exhibit 8. And I only have one copy. I'm going to look on with you.
THE WITNESS: All right.
MR. WALKER: I've only got one copy.
(Exhibit 8 marked for identification.)
BY MR. WALKER:
Q. If you'll turn the page. And then, on the third page, I think, essentially -- do you see that third page?
A. Yes.
Q. First of all, are you familiar with the Surgeon's Monograph that you're holding?
A. I am.
MR. BENTLEY: Objection, beyond the scope.

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A. I am.
Q. And how are you familiar with it?
A. This was used for some of the teaching programs that we had with cadaver labs.
Q. And was this a document that Ethicon provided to doctors not employed by the company?
A. Yes.
MR. BENTLEY: Objection, leading, scope.
Q. And how do you know that?
A. Because I saw them hand it out.
Q. And does this document contain information about appropriate patient selection for a Prolift procedure?
MR. BENTLEY: Objection.
A. It does.
Q. And does this document contain information about the risks or complications that are -- that can be associated with the Prolift device?
MR. BENTLEY: Objection, leading.
A. Yes.
Q. And is this a document that you reviewed and relied upon in forming your opinions about the adequacy of the information Ethicon provided to the medical community?

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MR. BENTLEY: Objection.
A. Yes.
Q. That's all for that document --
A. Okay.
Q. -- Doctor.
I direct your attention to page 14 of your report.
A. Okay.
Q. Do you remember being asked questions about the success rates --
A. Yes.
Q. -- of Prolift?
A. I'm sorry. Yes.
Q. And, Doctor, you have a chart on page 14 of your report; is that correct?
A. That's correct.
Q. What information does this chart contain?
A. This chart contains information from some randomized control trials that show the number of patients and the compartments that were treated with the Prolift procedure, mesh anatomical cure, native anatomical cure, and the clinical significance.
Q. And how many different studies are reflected in this chart?

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A. Nine.
Q. And are these all studies that you have reviewed and --
A. They are.
Q. -- relied upon?
A. They are.
Q. And what are the findings of these studies, in terms of the anatomic curative mesh versus native tissue repair?
A. They all were higher in the mesh repair versus the native tissue repair.
Q. I'm going to turn your attention to page 16 of your report, Doctor.
A. Um-hmm.
Q. Strike that. Let's go to page 15.
A. Okay.
Q. There was testimony about the two different Cochrane Reviews.
A. Right.
Q. Do you remember that?
A. Yes.
Q. And you're citing, here, from a Cochrane Review in 2013; is that correct?
A. That's correct.

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Q. And that's after Prolift was decommercialized; correct?
MR. BENTLEY: Objection.
A. Correct.
Q. And, Doctor, based on this meta-analysis, what was the failure rate of Prolift compared to native tissue or traditional repair?
A. I'm not seeing that on this.
Q. Oh, I'm sorry. I'm looking --
A. It just has cure rate and then mesh exposure rate.
Q. I'm sorry. I looking -- I'm not referring you to the chart.
A. Oh, I'm sorry.
Q. I'm sorry. Looking --
A. Okay.
Q. Looking --
A. Okay. Okay.
MR. WALKER: Can you repeat the question?
THE REPORTER: (Q) And, Doctor, based on this meta-analysis, what was the failure rate of Prolift compared to native tissue or traditional repair?
A. I think that's from the Altman.

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BY MR. WALKER:
Q. You're correct.
A. The Altman study. Okay. The Altman study has a randomized control trial with Prolift and native tissue. The failure rate with Prolift was 39 percent and the failure, with traditional, 65 percent. And that reached statistical significance.
Q. And you were initially asked some questions, I believe, regarding, you know, when you would want to use a Prolift to treat a patient prolapse.
Do you remember those types of questions?
A. I do.
Q. Why would a doctor like yourself choose to use a synthetic mesh product like Prolift instead of just relying on native tissue repair?
MR. BENTLEY: Objection.
A. Under certain circumstances, a synthetic mesh repair would probably be safer for a patient.
Q. And, Doctor --
A. And if we feel that there is a higher risk for a recurrence or a failure, then this would help.
Q. And how does Prolift help mitigate against the risk of a higher likelihood of recurrence?
MR. BENTLEY: Objection.

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A. With native tissue repair, you're using tissue that could already be damaged from previous whatever -- whatever issues that the patient had that caused her to develop the prolapse, whether it was childbirth or other surgeries, or anything like that. So by adding a synthetic reinforcement, you are now recreating a new support structure.
Q. And, Doctor, do you remember being asked questions about the ideal rate of erosion?
A. I do.
Q. And I believe the reference was made in your report to 8 percent being the ceiling, in terms of the ideal rate of erosion. Do you recall that?
A. 3 to 8 percent, yes.
Q. If you'll turn to page 16 of your report, Doctor.
A. Okay.
Q. Does your report cite any medical literature that documents an erosion rate in Prolift below 8 percent?
MR. BENTLEY: Objection.
A. Yes.
Q. And what are those pieces of medical literature?

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A. The Altman study had a 3.2 percent, De Landsheere study had a 2.5 percent, and the Benbouzoid had a 5.3 percent.
Q. And then, Doctor, have there been any long-term studies that have looked at Prolift?
A. There have been.
Q. Did you review and rely upon any of those, in formulating your opinions and drafting your report?
A. I did.
Q. Specifically, which ones?
A. There's a seven-year follow-up and -- the Maher follow-up.
Q. What was the conclusion of the Maher follow-up of seven years?
A. Their conclusions were, "Women undergoing transvaginal mesh prolapse surgery using synthetic graft continue to have positive objective and subjective outcomes leading to significantly improved quality of life at five-year follow-up."
MR. BENTLEY: What exhibit was that from?
MR. WALKER: It was just from his report, page 17. Bottom of 16 and page 17.
BY MR. WALKER:
Q. Doctor, do you remember being asked questions

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about the relevance of TVT, TVT-O, and TVT literature, in formulating your opinions about the biocompatibility of mesh?
A. Yes.
Q. Doctor, would you agree that TVT and TVT-O are made of Prolene?
A. Yes.
Q. And would you also agree that Prolift is also made of Prolene, just in a different construction?
MR. BENTLEY: Objection.
A. Yes.
Q. So why, then, do you believe that the TVT literature is relevant, in terms of whether or not the Prolift mesh is suitable in terms of its biocompatibility?
MR. BENTLEY: Objection.
A. Because it's made from the same material.
Q. From your review of the medical literature, what opinions have you formed regarding the biocompatibility of the mesh in Prolift?
A. I think it's biocompatible.
Q. And upon what do you base that opinion?
A. On the medical literature and studies that I've cited here.

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MR. BENTLEY: Objection, vague.
Q. Doctor, do you remember being shown the Clavé study, regarding degradation of polypropylene?
A. Yes.
Q. And, Doctor, is the Clavé article a meta-analysis?
A. No.
Q. Is it a randomized control trial?
A. No.
MR. BENTLEY: Leading.
Q. And do you remember being shown, Doctor, the article on degradation of polypropylene in vivo by Vladimir Iakovlev and Scott Guelcher?
A. Yes.
Q. Doctor, are you familiar with either of these two authors?
A. Personally, no.
Q. And in terms of your consultation in these cases, are you familiar --
A. Yes.
Q. -- with these individuals?
A. Yes.
Q. How so?
A. I have read their articles or reviewed some

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of their publications.
Q. And do you recall either reviewing or seeing any expert reports from Dr. Iakovlev?
MR. BENTLEY: Leading.
A. No.
Q. Are you aware that Dr. Iakovlev and Dr. Guelcher are designated experts for the plaintiffs in the mesh litigation?
MR. BENTLEY: Leading.
A. Actually, I am now aware Iakovlev is, I think. I knew that one.
Q. And, Doctor, if you could -- do you have that exhibit in front of you?
A. No. I can get it. What exhibit is it?
Q. I frankly don't remember.
A. Okay. Iakovlev. Got it.
Q. Doctor, if you'll turn to page 11.
A. Um-hmm.
Q. Do you see the section titled "Acknowledgments"?
A. Yes.
Q. Doctor, do either of these two doctors disclose, in this article, that they are paid experts for the plaintiffs --

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MR. BENTLEY: Objection.
Q. -- in the mesh litigation?
A. No.
Q. And the date of this article is rather recent, correct, Doctor?
MR. BENTLEY: Objection.
A. July 2015, yes.
Q. In your review of the medical literature, are you aware of any meta-analysis looking at Prolene mesh products that has concluded that Prolene degrades in any kind of clinically meaningful way?
MR. BENTLEY: Objection.
A. No.
Q. Are you aware of any randomized control trial that has concluded that Prolene mesh degrades in any kind of clinically meaningful way?
MR. BENTLEY: Objection.
A. No.
Q. In your practice, have you seen degradation of Prolene cause any clinically significant outcomes in your patients?
MR. BENTLEY: Objection.
A. No.
Q. Have you reviewed or seen any medical

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literature that comes to the conclusion that degradation of Prolene actually causes any kind of clinical harm in any circumstance?
MR. BENTLEY: Objection.
A. No.
Q. And that's, Doctor, after reviewing a multitude of meta-analysis and randomized control trials relating to both TVT and Prolift?
MR. BENTLEY: Objection.
A. Correct.
Q. And, Doctor, you've seen, in the Clavé study and the article by Iakovlev, the word "polypropylene" used --
A. Yes.
Q. -- throughout; is that correct?
A. Yes.
Q. And we've also talked about how the mesh products by Ethicon are made of Prolene; correct?
MR. BENTLEY: Objection.
A. That's correct.
Q. Do you know what the difference is between polypropylene and Prolene?
A. Yes.
Q. And what is that difference?

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A. Polypropylene -- they have added oxidizing agents to the polypropylene.
Q. It's late. I think you got that --
A. Oh.
Q. -- convoluted.
A. Maybe the other way. Yeah, you're right.
Q. Let's try that again.
What is the difference between polypropylene and Prolene?
MR. BENTLEY: Objection.
A. Polypropylene has the oxidate -- the oxidizing agents added to it.
Q. Doctor, do you remember reviewing any internal company documents that reflected the ingredients of Prolene?
A. Yes.
Q. And do you recall how anti-oxidizing ingredients were added to Prolene?
A. Prolene, to get polypropylene.
MR. BENTLEY: Objection.
A. Right. Isn't that what I said?
MR. BENTLEY: Objection.
THE WITNESS: Objection. Can I breathe, or you are you going to object to that, too?

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MR. WALKER: It's late. It's late. We're almost there.
THE WITNESS: Okay.
BY MR. WALKER:
Q. You were asked a number of questions about Ethicon's decision to decommercialize Prolift. Do you recall that?
A. I do.
Q. And I believe you testified that their decision to decommercialize Prolift doesn't impact any of your opinions regarding the safety and efficacy of Prolift. Is that correct?
MR. BENTLEY: Objection.
A. That's correct.
Q. Why is that?
A. Because all my patients that I have implanted with Prolift or have seen with Prolift have done very, very well. So I have a positive result with it.
Q. Does Ethicon's decision, in 2012, to decommercialize Prolift, have any bearing on the integrity of the data that's reflected in the medical literature that you've reviewed?
MR. BENTLEY: Objection.
A. No.

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Q. Doctor, you were asked a number of questions about life-altering complications. Do you remember that?
A. Very vividly.
Q. Doctor, is it fair to say that complications can be either short-term or long-term?
A. Yes.
MR. BENTLEY: Objection.
Q. And are potential lifelong complications something that's unique to Prolift surgery?
MR. BENTLEY: Objection.
A. No.
Q. And how do you know that?
A. I know that because I've seen lifelong complications from traditional repairs and other repairs that we do that are not mesh.
Q. Doctor, you were asked questions about the frequency of complications.
A. Yes.
Q. Do you remember that?
A. Yes.
Q. Is there more data in the medical literature regarding the frequency of complications for native tissue repair or for the Prolift procedure?

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MR. BENTLEY: Objection.
A. Is there more -- repeat the question again.
Q. Do you know if -- I'll slightly rephrase it.
A. Okay.
Q. Do you know if there's more data in the medical literature, regarding the frequency of complications of native tissue repair or Prolift surgery?
MR. BENTLEY: Objection.
A. I do not.
Q. Okay. You talked earlier about standardization that came with mesh kits like Prolift. Do you remember that?
A. Yes.
Q. And what is the relationship between the standardization of mesh kits and surgery to the quality of the data that you can gather from those procedures?
A. It's much more accurate and scientific, because now you're comparing two exactly same procedures versus theoretically comparing the same procedures.
Q. Do you remember, Doctor, being asked questions about mesh shrinkage --
A. Yes.
Q. -- or contraction?

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A. Yes.
Q. And you testified, I believe, that you are not of the opinion that the mesh, itself, shrinks; is that correct?
MR. BENTLEY: Objection.
A. Yes.
Q. And what is the basis for that opinion?
A. Studies that have looked at ultrasounds after mesh implantation over a long period of time and showed no change in the size of the mesh.
Q. Doctor, I believe you said that if there is anything happening in terms of shrinkage or contraction, it's a function of tissue and not of the mesh; is that accurate?
MR. BENTLEY: Objection.
A. That's accurate.
Q. And what is your basis for saying that tissue contraction, as opposed to mesh contraction, is taking place?
MR. BENTLEY: Objection.
A. Because studies have showed that the mesh does not change in shape or size, but the tissue, when it incorporates into the mesh, will cause some scarring and some contraction. The tissue.

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Q. I want to go back to the topic of complications that are unique to mesh.
Is pelvic pain, in your opinion, Doctor, a complication that is unique to Prolift?
MR. BENTLEY: Objection.
A. No.
Q. Is dyspareunia a complication that is unique to Prolift?
A. No.
Q. Is scarring a complication that is unique to Prolift?
MR. BENTLEY: Objection.
A. No.
Q. Is infection a complication that is unique to Prolift?
MR. BENTLEY: Same objection.
A. No.
Q. And, Doctor, with what types of pelvic floor surgeries can those complications I just asked you about occur?
A. Any pelvic floor surgery.
Q. So when we're talking about complications that are unique to mesh, what are you referring to?
A. Erosions and extrusions.

Q. And in terms of erosions and extrusions, can you have those complications in a native tissue repair utilizing sutures?

A. That's correct.

MR. BENTLEY: Objection.

A. Yes.

MR. WALKER: Were almost done. I'm making sure I got everything.

That's all I have. Thank you.

FURTHER EXAMINATION

BY MR. BENTLEY:

Q. Doctor, you discussed the Altman study. Do you remember that?

A. Yes.

Q. Do you know that the Altman study was included in the 2016 Cochrane Review?

A. Yes.

Q. And the Altman study is a lower level of evidence, as compared to systematic reviews like the 2016 Cochrane Review; correct?

A. Yes.

Q. And, in fact, the 2016 Cochrane Review is a higher level of evidence than the De Landsheere study and the Benbouzoid study; correct?

A. Correct.

Q. Doctor, you were asked some questions about the Iakovlev study. Do you remember that?

A. Yes.

Q. And if you'd just look at the second-to-last page. You were asked whether there were some disclosures by the authors.

Under "Acknowledgments," do you see that the authors, in fact, disclosed that they're working as consultants in this litigation?

A. "Others provided expert opinions for medicolegal cases in matters related to polypropylene mesh."

Q. You'd agree, they made an accurate and honest disclosure; correct?

A. That's what it says here, yeah.

Q. So other than that, do you have any other reason to discount their findings in this peer-reviewed published article?

A. Other than what we talked about earlier.

Q. As you sit here today, can you tell the jury any reason why you discount the findings in this article -- specifically in this article?

A. That it's not a randomized control trial,

yes.

MR. BENTLEY: Thank you, Doctor. I have no further questions.

MR. WALKER: Okay. We're done.

THE REPORTER: Signature, Doctor?

THE WITNESS: Yes, ma'am.

DEPOSITION CONCLUDED AT 9:30 P.M.

CERTIFICATE

State of Ohio :
: SS
State at Large :

I, Teresa A. Moore, RPR, CRR, the undersigned, a duly commissioned notary public within and for the State of Ohio, do hereby certify that before the giving of his aforesaid deposition, MICHAEL KARRAM, M.D. was by me first duly sworn to depose the truth, the whole truth and nothing but the truth; that the foregoing is the deposition given at said time and place by MICHAEL KARRAM, M.D.; that said deposition was taken in all respects pursuant to stipulations of counsel; that I am neither a relative of nor employee of any of their parties or their counsel, and have no interest whatever in the result of the action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal of office on this 5th day of July, 2016.

TERESA A. MOORE
Notary Public - State of Ohio
My Commission expires: 06/17/21

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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